A STUDY EXPLORING THE RELATIONSHIPS BETWEEN DIABETIC FOOT ULCER PAIN AND HEALTH-RELATED QUALITY OF LIFE AND FUNCTIONAL STATUS OF PEOPLE AGED SIXTY YEARS AND OVER IN MALAYSIA

Thesis submitted for the degree of Doctor of Philosophy

by

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DEDICATION

Dedicated to my late father, my mother, my husband and my sons for their love, sacrifice and inspiration.

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In the name of Allah most gracious most merciful

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THESIS SUMMARY

Background: Diabetic foot ulcers are often described as painless due to peripheral neuropathy. The literature reveals that pain poses a significant problem than expected and severely affects the patient's quality of life and functional status. There has been no research conducted in Malaysia on this aspect of the disease. The relationships between diabetic foot ulcer pain and health-related quality of life and functional status in people over sixty years in Malaysia is needed to understand the problem.

Aims: To investigate the relationships between diabetic foot ulcer pain and health-related quality of life and functional status in people over sixty years in Malaysia.

Methods: In a cross-sectional comparative study, 300 people over sixty years with diabetic foot ulcers were recruited from two secondary care (Clinic S) and three primary care clinics (Clinic P) in Malaysia. An interviewer-administered questionnaire was used to collect data. Five validated Malay versions of questionnaires were used: a short-form McGill pain questionnaire (SF-MPQ) to measure diabetic foot ulcer pain, the medical outcome study 36-items short-form health survey (SF-36) and the diabetic foot ulcer scale short-form (DFS-SF) to measure health-related quality of life, Katz activities of daily living (Katz ADL) and Lawton instrumental activities of daily living (Lawton IADL) to measure functional status. Data were encoded, entered onto a computer, and analysed with SPSS 21.0 software.

Results: All the participants experienced diabetic foot ulcer pain. Diabetic foot ulcer pain was worse in married females, more than three health problems, having a 3rd episode of foot ulcer, having Grade 4 foot ulcers, using anti-microbial dressing and sterile water. The health-related quality of life and functional status worsened with increasing pain. Multiple linear regression showed that being female, having a Grade 4 foot ulcer, using sterile water, using anti-microbial dressing, bodily pain and bothered by ulcer care significantly contributed to diabetic foot ulcer pain. Participants in Clinic S reported much more pain compared to participants in Clinic P.

Conclusion: This study has demonstrated that a holistic approach is needed when managing patients with diabetic foot ulcer pain. Additionally, this study identified areas that can be improved when providing treatment and implementing wound prevention programs for diabetic patients.

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LIST OF ABBREVIATIONS

AAOS	American Academy of Orthopaedic Surgeons Musculoskeletal Outcomes Measure
ADA	American Diabetes Association
ADL	Activities of Daily Living
CASP	Critical Appraisal Skills Programme
CDC	Centers for Disease Control and Prevention
CWIS	Cardiff Wound Impact Schedule
DFS	Diabetic Foot Ulcer Scale
DFS-SF	Diabetic Foot Ulcer Scale- Short Form
EQ-5D	Euro-QoL-5D
HbA1c	Glycosylated haemoglobin
HOD	Head of Department
IADL	Instrumental Activities of Daily Living Scale
IASP	International Association of the Study of Pain
IDF	International Diabetes Federation
IQR	Interquartile Range
NCD	Non communicable diseases
NHMS	National Health and Morbidity Survey
PHRU	Public Health Resource Unit
PHMB	Polyhexamethylene Biguanide Antimicrobial Foam Dressing
PPI	Present Pain Index
PRI	Pain Rating Index
RAND-36	Research and Development 36-item Form

LIST OF ABBREVIATIONS (Continued)

RCT	Randomised Controlled Trial
SD	Standard Deviation
SF- MPQ	Short-Form McGill Pain Questionnaire
SF-12	The Medical Outcomes Survey Short-Form 12
SF-36	The Medical Outcomes Study 36-item Short-Form Health Survey
s-LANSS	Leeds Assessment of Neuropathic Symptoms and Signs Questionnaire
VAS	Visual Analogue Scale
VRS	Verbal Rating Score
WHO	World Health Organization
WHOQOL-G	World Health Organisation Quality of Life Group
WUWHS	World Union of Wound Healing Societies

CHAPTER 1

INTRODUCTION

1.1 Introduction

Diabetic foot ulcers are one of the major concerns of the complications of chronic diabetes mellitus, especially among the older population. Diabetic foot ulcers have been found to affect health-related quality of life in various dimensions, such as physically, mentally, socially, and economically (Ribu and Wahl 2004; Evans and Pinzur 2005). Pain is common in patients living with chronic wounds, such as pressure ulcers, venous ulcers, and ischemic ulcers (Mudge and Orsted 2010). Similar to other chronic wounds, diabetic foot ulcers can result in pain, which has been reported to adversely affect health-related quality of life and functional status (Ribu et al. 2006; Bradbury and Price 2011b; Bradbury and Price 2011c (phase 2). While there is much research into pain in other chronic wounds, examining pain in diabetic foot ulcers is not an area which is widely explored.

This chapter describes the background of the study, the current scenario in Malaysia on population ageing, diabetic mellitus, and diabetic foot ulcers. The health care system in Malaysia is also discussed in this chapter. The problem statement of this thesis, the study objectives, and the research questions, and the significance of the study are presented at the end of this chapter.

1.2 Study background

The world population is ageing as a result of increased life expectancy, lower fertility, and better health care services (United Nations 2013). Population ageing is happening in all regions of the world, with the older population in developing countries having a higher speed of growth compared to in developed countries (National Institute on Aging 2010). This obviously affects a society's economic and social structures, as well as its health care system. Ageing brings an increased risk of developing chronic non-communicable diseases (NCDs) such as hypertension, type 2 diabetes mellitus, stroke, and

coronary heart disease (Wild et al. 2004). As a result, the health care burden in most nations will increase. Globally, at present, these chronic diseases are identified as being among the ten leading causes of death (World Health Organization (WHO) 2015).

With the growing number of older people diagnosed with diabetes mellitus, Malaysia is not spared this phenomenon, as the prevalence of diabetes mellitus stands at 15.2% of the adult population (National Health and Morbidity Survey (NHMS 2011)). Two-thirds of the 177 million people with type 2 diabetes mellitus are estimated to live in the developing world (International Diabetes Federation 2013). The greatest increase in the prevalence of type 2 diabetes mellitus in older people is expected to occur in Asia and Africa, due to urbanisation and changes in lifestyle (Wild et al. 2004). Diabetes mellitus causes significant morbidity, disability, and mortality among older people (Gambert and Pinkstaff 2006). Its effects will increase health care costs to the patient, the community, and the nation (Hogan et al. 2003).

Diabetic foot ulcers are well known to be the most costly and devastating complication of diabetes mellitus due to the complexity of wound treatment and because they are a major reason for non-traumatic amputation (International Diabetes Federation 2013). The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25 % (Singh et al. 2005). As a result, it will cause substantial morbidity and impaired quality of life; it is the most important risk factor for lower-extremity amputation and results in high treatment costs and enormous economic losses (Margolis et al. 2005). As Malaysia's population is ageing and there is a rising prevalence of diabetes, it is expected that the number of diabetic foot ulcer patients will also increase substantially.

Although there is a general misconception that pain or discomfort does not occur in diabetic foot ulcer patients, this is not entirely true for all patients, who despite having peripheral neuropathy, may report severe and frequent pain (Baker 2012).

Bradbury and Price (2011a) and Bradbury and Price (2011c [phase 1]) carried out a research to investigate the presence and characteristics of diabetic foot ulcer pain in 28 diabetic foot ulcer patients, and it was found that 86% (n=24)

had diabetic foot ulcer pain. It occurs frequently and with high intensity despite peripheral neuropathy and in most cases, patients describe aching as the most common sensory pain. In addition, studies by Ribu et al. (2006) and Obilor and Adejumo (2014) suggested that specific ulcer pain from diabetic foot ulcers is more prevalent than expected and can affect the patient's quality of life. More extensive research is required to fully understand and adequately manage this phenomenon in clinical practice.

These issues prompted the researcher to perform a cross-sectional comparative study to investigate the relationships between diabetic foot ulcer pain and health-related quality of life and functional status in people over sixty years in Malaysia. The main aim is to enhance knowledge and understanding and contribute to improving the standards of patient care.

1.3 About Malaysia

Malaysia is a federation of states, and it practices a parliamentary democracy, with the Prime Minister as the head of the government and the constitutional monarch elected from amongst the sultans.

Malaysia is located in South East Asia, between latitudes 2° and 7° North of the Equator and longitudes 100° and 119° East. It consists of two regions: Peninsular Malaysia, on the Asian mainland, and the states of Sarawak and Sabah, known as East Malaysia, on the island of Borneo. Peninsular Malaysia is separated from the states of Sabah and Sarawak by the South China Sea. To the north of Peninsular Malaysia is Thailand, while its southern neighbour is Singapore. Sabah and Sarawak share a common border with Indonesia, while Sarawak also shares a border with Brunei. It is made up of 13 states and three federal territories.

The total land area of the country is 329,960 square kilometres, with Peninsular Malaysia occupying an area of 131,805 km^2, Sabah including the Federal Territory of Labuan occupying 73,997 km2 and Sarawak occupying124,450 km^2. Malaysia is a tropical country with an equatorial climate; thus, as the climate is influenced by the monsoon seasons, it is hot and humid throughout the year, with average temperatures ranging between 21°C to 32°C and with an annual rainfall of 2000 mm to 2500 mm (Kamaliah and Safurah 2011). The

capital city is Kuala Lumpur, while Putrajaya is the seat of the federal government.

In 2010, the total population of Malaysia was 28.5 million, and the population growth rate was 1.72%. Malaysia is a multi-ethnic country, with the Malays being the majority (60%), followed by the Chinese (23%), the indigenous people (10%), and the Indians (7%). The state with the highest population was Selangor (5.4 million) while Perlis had the lowest population (227,000). From 1980 to 2009, the percentage of urbanization increased from 25% to 62% (Department of Statistics Malaysia 2010).

Islam is the official and predominant religion in Malaysia, and it is practiced by 60% of the population. Malay (Bahasa Melayu) is the official language and is spoken in all areas of the country.

Figure 1. 1 Malaysia Map

Source: (http://www.malaysia-maps.com/images/map-malaysia600.gif)

1.4 The ageing population in Malaysia

The total world population has increased dramatically from 2.5 billion in 1950 to 6.9 billion in 2010 (United Nations 2011). This population trend is due to changes in the fertility rate and mortality rates, as well as improved public health services (United Nations 2002). According to WHO, the world population aged 60 years and above was 650 million by 2011, and it is projected to reach 2 billion by 2050 (WHO 2011). Furthermore, it is expected that the number of

older people living in the low and middle-income countries will increase to 80% by 2050 compared to 60% in 2005 (United Nations 2010).

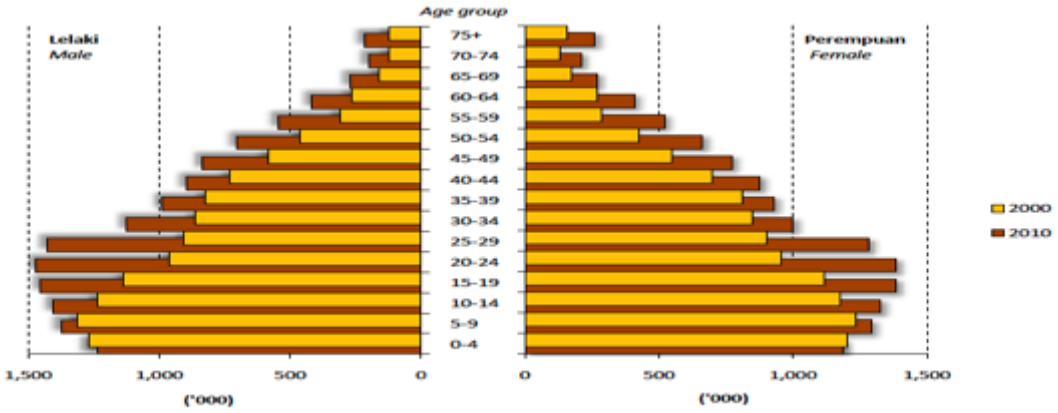
Like many countries in the region, Malaysia is also experiencing an increase in its ageing population, as illustrated in Figure 1.2. The percentage of the younger population (aged less than 15 years) has decreased over the past 10 years. In 2010, the younger population comprised 27.6% of the population compared to 33.3% in 2000 (Department of Statistics Malaysia 2010). In addition, the median age of the Malaysian population increased from 23.6 years in 2000 to 26.2 years in 2010. In national policies, Malaysia defines older people as those aged 60 years or above, based on the recognition attained from the "World Assembly on Aging 1982" in Vienna (Department of Social Welfare Malaysia 2012). The population of older Malaysians was 2.25 million (7.4%) in 2010 compared to 1.40 million (6.3%) in 2000 (Department of Statistics Malaysia 2010; Ong et al. 2009). It is expected that the percentage of older people aged 60 and above in Malaysia will increase from 6.6% in 2000 to 20.8% in 2050 (United Nations 2002).

As a developing country, Malaysia has achieved a better socioeconomic and health status for its population over the last fifty years. Therefore, the life expectancy has improved for both Malaysian men and women (Ministry of Health Malaysia 2010). Life expectancy for men increased from 68.9 years in 1990 to 72.5 years in 2010. Similarly, women's life expectancy has increased from 73.5 years in 1990 to 76.9 years in 2010. These trends indicate a transition of the age structure towards an ageing population in Malaysia.

As the population of older people in Malaysia grows, there will be impacts not only on Malaysia's economic and social structures, but also on its health care system (WHO 2011). This is because older people are at risk of developing chronic NCDs. The top three leading NCDs in Malaysia are hypertension, diabetes mellitus, and hyperdyslipidemia. This will subsequently result in an increased health care burden, as these conditions may lead to significant cardiovascular diseases. These diseases are amongst the commonest causes of death in Malaysia (Ministry of Health Malaysia 2008a). In addition, the presence of chronic NCDs among older people is associated with lower health-related quality of life (Sazlina et al. 2012), which could reduce independence

and healthy productive ageing, which are the goals of successful ageing for many nations.

Figure 1. 2 Population pyramid by sex and age group in Malaysia, 2000 and 2010



(Source: Department of Statistics Malaysia 2010)

1.5 Diabetes mellitus in Malaysia

Diabetes mellitus is one of the most common NCDs globally. It has become the greatest concern, as its prevalence is rapidly escalating worldwide, especially in developing and newly industrialised countries (Rugayah 2007). In 2010, 285 million (6.4%) adults were diagnosed with diabetes, and this is projected to increase to 439 million (7.7%) by 2030 (Shaw et al. 2010).

Diabetes mellitus is a major cause of morbidity, as well as mortality, and contributes substantially to health care costs to the patient and to the country's health system and economy (Hogan et al. 2003; WHO 2002). In 2010, the International Diabetes Federation estimated that US dollars (USD) 376 billion was spent on treating and preventing diabetes mellitus, which translates as 11.6% of the total health care expenditure worldwide (Whiting et al. 2011). After three years, the International Diabetes Federation (2013) reported that this figure had increased to USD 548 billion.

Although the European region currently has the highest number of diabetes sufferers (48 million people), it is forecast that this chronic disease will increase greatly in Asian regions in less than 25 years (International Diabetes Federation 2013). It is estimated that by 2025, the total number of diabetes sufferers in the

Southeast Asian region will reach a peak of more than 170 million (Wild et al. 2004). The rising trend in the prevalence of diabetes mellitus is due to an ageing population, unhealthy diet, obesity, sedentary lifestyle, and the economic development and urbanisation of the countries in this region (Zanariah et al. 2008; International Diabetes Federation 2013).

Malaysia, which is located in Southeast Asia, is categorised as a developing country with a population of 28.5 million (Department of Statistics Malaysia 2010). The country is highly prone to diabetes epidemics. In 2010, Malaysia was ranked tenth in the world for the percentage of adults living with diabetes (11.6%). This is higher than Singapore (10.2%), Japan (5.0%), the United States (10.3%), the United Kingdom (3.6%), and Australia (5.7%) (Shaw et al. 2010). In 2008, Zanariah et al. (2008) stated that one in six Malaysians above the age of 30 years old had diabetes mellitus and that the prevalence of diabetes mellitus in Malaysia had increased rapidly due to many factors, such as rapid socio-economic growth, urbanisation, sedentary lifestyle, changes in nutritional habits with a high intake of carbohydrates and saturated fats, and an increased proportion of the population who are overweight or obese (Ismail et al. 2002; Letchuman et al. 2010).

The first National Health and Morbidity Survey (NHMS) in 1986 reported a 6.3% prevalence of diabetes in the population aged 30 and above (Ministry of Health Malaysia 2008b). This number kept climbing to 8.3% after the second NHMS in 1996 and 14.9% in 2006 in the population aged 30 and above (Letchuman et al. 2010; Zaini 2000). The most recent NHMS (2011) revealed that the prevalence of diabetes patients had increased to 15.2% (2.6 million) among adults aged 18 years and above (Kaur et al. 2011). Of this 15.2%, 7.2% were known to have diabetes, and 8.0% had been previously undiagnosed with diabetes in Malaysia. Among the diabetes population in Malaysia, the Indians have the highest prevalence (24.9%), followed by the Malays (16.9%) and lastly, the Chinese (13.8%). The 2011 NHMS has estimated that in 2020, Malaysia will have approximately 4.5 million people with diabetes (Ministry of Health Malaysia 2011). Interestingly, WHO has projected that in 2030, Malaysia will have a total of 24.8 million people with diabetes (Ministry of Health Malaysia 2011) of a projected Malaysia population of 36 million (Department of Statistics Malaysia 2013).

Studies by Porapakkham et al. (2008) and Margaret et al. (2009) have shown that the proportions of populations affected by diabetic mellitus are increasing in the countries that have higher percentages of ageing societies. Diabetes mellitus in people over 65 years old has been projected to increase by 56% between 2002 and 2020 in the Unites States (Caspersen et al. 2012). In the United Kingdom, the prevalence of older people with diabetes mellitus was estimated to be between 11% and 14% (Jerums et al. 2009). The situation in Malaysia is parallel to that of other countries; a study by Rampal et al. (2010) demonstrated that the prevalence of diabetes was lowest (8.5%) in the 30-39 years age group and increased steadily with age to 22.7% for those who were over 60 years old. In a recent study by Ho et al. (2014), it was revealed that in Malaysia, the prevalence of diabetes mellitus among older persons was high, at 34.4%, compared to 20.8% for the adult population aged 30 years and more (NHMS 2011). Therefore, the burden due to diabetes mellitus is likely to rise steadily in Malaysia as a result of population ageing (Porapakkham et al. 2008).

Poor glycaemic control leads to long-term complications and contributes to a significant rate of mortality and morbidity. Glycaemic control among Malaysian adults with diabetes mellitus remains poor (based on the level of glycosylated haemoglobin (HbA1c) of lower than 7%). Previous studies in Malaysia have revealed a high prevalence of suboptimal glycaemic control and have shown that diabetes mellitus complications are common (Mafauzy 2005; Mafauzy 2006). The proportion of people over 18 years old with HbA1c of 7.0% and above in both primary and tertiary care centres is between 59.0% and 80.0% (Mafauzy 2005; Mafauzy 2006; Mastura et al. 2011). Similarly, the proportion of people aged 60 years and above with HbA1c of 7.0% and above is 56.3 % (Sazlina et al. 2015). There was also a high prevalence of diabetic complications; for example, 4.3% of diabetes mellitus patients had undergone lower limb amputations, 3.4% had suffered strokes, and 1.6% were on dialysis or had been given kidney transplants due to micro-vascular complications. In addition, late presentation to the hospital and delayed treatment were other reasons for complications and poorly controlled diabetes mellitus (Rampal et al. 2010). On the other hand, active screening for diabetes complications, for example, screening for microalbuminuria and neurology testing, were not routinely practiced by many health care providers in Malaysia (Rampal et al.

2010). Therefore, this situation has resulted in a high level of complications among patients with diabetes mellitus in Malaysia.

1.6 Diabetic foot ulcers in Malaysia

Patients with diabetes mellitus are prone to multiple complications, such as diabetic foot ulcers. Diabetic foot ulcers are one of the most common long-term diabetes-related complications that have shown an increasing trend over previous decades (Cavanagh et al. 2005; Alavi et al. 2014). This disease has resulted in an increased hospital bed occupancy and accounts for increasing healthcare cost and resources (Girod et al. 2003). Such complications are often associated with disability and the impairment of health-related quality of life both in developed and developing countries (Vileikyte 2001; Moulik and Gill 2002; Boulton et al. 2005; Nabuurs-Franssen 2005).

The approximate chance of a diabetic person developing a foot ulcer in their lives has been estimated at 15–25% (Singh et al. 2005). A review has shown that the worldwide annual population-based incidence of diabetic foot ulcers ranges from 1 % to 4.1%, and the prevalence ranges from 4% to 10% (Singh et al. 2005). In the United States, the American Diabetes Association (ADA) has revealed that up to 25% of people with diabetes will experience a foot ulcer at some point in their lifetime. In the United Kingdom, it is estimated that there are around 64,000 persons with active foot ulceration and 2,600 amputations annually in patients with foot ulcers (Gordois et al. 2003). In Malaysia, the prevalence of foot ulceration in participants who were attending a diabetic outpatient clinic was 6.0% (Ministry of Health Malaysia 2004). Surprisingly, a recent study conducted by Mazlina et al. (2011) to assess the health-related quality of life of 140 diabetic participants with foot problems attending outpatient diabetic foot clinics in a tertiary hospital showed that 47.1% of the patients had foot ulcers. These statistics highlight the necessity for an increased awareness of diabetic foot problems in Malaysia.

Predisposing factors leading to diabetic foot ulcers include peripheral neuropathy and peripheral vascular diseases, which are known to be at high risk of foot complications (Shojaiefard et al. 2008). It has been suggested that up to half of the patients with diabetes mellitus will experience neuropathy, with

prevalence increasing with age, duration of the disease, and degree of glycaemic control (Boultan 2002; Boultan et al. 2005). Peripheral neuropathy can lead to the development of neuropathic pain. In a study by Davies et al. (2006), which investigated the prevalence, severity, and impacts of painful diabetic peripheral neuropathy, it was found that 80% of the patients experienced moderate to severe pain. The most common complaints are hot, burning, sharp, and electric or tingling pains (Galer et al. 2000; Boultan 2004).

Apart from the condition of peripheral neuropathy and peripheral vascular disease, diabetic foot ulcers can be caused by risky behaviours such as walking barefoot, wearing inappropriate footwear, burns, and neglect of foot self-care (Gale et al. 2008; Ogbera et al. 2008; Iversen et al. 2009). Furthermore, foot deformities and abnormalities, such as flatfoot, hallux valgus, claw toes, Charcot neuropathy and hammer foot, may result in high focal foot pressures and an increased risk of ulceration (Tesfaye et al. 1996; Alexiadou and Doupis 2012). Other factors that commonly contribute to the risks of ulceration include a previous history of foot ulceration or amputation, visual impairment, diabetic nephropathy and cigarette smoking (Alexiadou and Doupis 2012). Social factors, such as low socioeconomic status, poor access to healthcare services, and poor education, also play important roles in the pathway of diabetic foot ulcers (Benotmane et al. 2000; Prompers et al. 2006). Risk factors related to foot ulceration in individuals with diabetes mellitus should be detected as early as possible and assessed in an effort to eliminate any actual or potential complications of foot problems (Ogbera et al. 2008).

The wound healing and prevention of complications are the principle aims of wound management (McDowell et al. 2007). Treatment of diabetic wounds includes diagnosis, offloading, infection control, wound bed preparation, dressings, surgery, adjuvant agents (topical, device, systemic) and prevention of recurrence (Steed et al. 2006). Wound assessment is essential in order to establish the cause and the factors involved in the development of the ulcer (Myles 2007). When an ulcer develops, the health care provider must perform a thorough wound assessment; correct diagnosis and effective documentation are essential to treat wounds effectively (Eagle 2009). In case of pressure, off-loading is a treatment to reduce the pressure to the diabetic foot ulcer, thus reducing the trauma to the ulcer, which is extremely important for the healing of

plantar ulcers (Ministry of Health Malaysia 2004; Hasniza 2015). Infection control also plays an important role in wound healing. According to Hasniza (2015), various microorganisms may colonize the wound and cause further tissue damage. Diabetic foot infection may start superficially in an ulcer or crack of the skin and can then spread contiguously, including into deeper tissues, often reaching the bone (Hasniza 2015). Removing infection, calluses or necrotic tissue can be done by mechanical means (high pressure irrigation), biosurgical means (sterile maggots), enzymatic means (topical enzymes), chemical means (caustic agents), or surgical debridement (Steed et al. 2006; Internal Best Practice Guideline 2013). Debridement should be carried out in all chronic wounds to remove surface debris and necrotic tissue (Myles 2007; Alexiadou and Doupis 2012) and to promote wound healing. Wound dressings should maintain a moist wound environment. A moist wound–healing environment promotes the healing of wounds and reduces pain (Steed et al. 2006; International Best Practice Guideline 2013).

1.7 General overview of the healthcare system in Malaysia

Malaysia has one of the best healthcare systems in the region, and Malaysia's health status has improved significantly since its independence in 1957 (Ministry of Health Malaysia 2005).

Malaysia's healthcare system is divided into two sectors, namely, the public and the private sector. The Ministry of Health Malaysia is the main provider of health services in the country, and the services are designated at three levels, that is, primary, secondary, and tertiary levels of care, and are highly subsidized by the government. The services offered are comprehensive, comprising health promotion, and preventive, curative, and rehabilitative services.

There are four types of public hospitals under the Ministry of Health Malaysia, namely, state general hospitals, district hospitals, and special institutions, and national referral medical institutions. There are also non-Ministry of Health Malaysia hospitals. Each of Malaysia's fourteen state capitals has a general hospital, with 600 to 700 beds each, providing a full range of healthcare services. District hospitals, which are much smaller, have 250 to 400 beds each, providing a more basic diagnostic and curative healthcare service. The

National Referral Centre is the highest level of hospital in the hierarchy. This hospital has 2,800 beds and is located in Kuala Lumpur, although it receives referrals from other parts of the country, especially for cases that require specialized care that is not available in state general hospitals, such as in neurosurgery and radiotherapy.

A seamless referral system links the different levels of care in the public system. The referral system connects primary healthcare facilities with the hospitals (at both district and state level) and specialist centres (Ministry of Health Malaysia 2008b). According to Chew et al. (2014), through this referral system, patients can enter into the public health system at any healthcare facility and will be referred to any other healthcare facility for further medical or surgical care including by the clinical specialist at the hospital. In 2011, there were 138 public hospitals (with a total 38,394 beds), 985 health clinics, 1,864 community clinics, 1,091 Malaysia clinics, 51 dental clinics and 184 mobile health teams (Ministry of Health Malaysia 2012b). Table 1.1 shows the various types of health facilities in the Malaysian healthcare system by public health sector.

The Ministry of Education of Malaysia also complements the Ministry of Health Malaysia in terms of shared services and facilities. There are a number of University Hospitals which provide public healthcare services in collaboration with the Ministry of Higher Education Malaysia, for example, University Malaya Medical Centre (UMMC), Universiti Kebangsaan Malaysia Medical Centre (UKMMC), and University Sains Malaysia Medical Centre (USMMC). These hospitals provide services, the training of health personnel, and research on health. Other ministries that are also involved in healthcare provision include the Ministry of Defence, which maintains health facilities mainly catering to the health needs of the military personnel and their families; the Department of Aboriginal Affairs of the Ministry of National Unity and Social Development, which provides health services for the aborigines; and the Ministry of Housing and Local Government, which provides environmental health services within the local council boundaries. The Department of Social Welfare from the Ministry of Women, Family and Community Development provides long-term care for the indigent and elderly in a number of welfare homes, while the Ministry of Home Affairs manages several drug rehabilitation centres in the country (Ministry of Health Malaysia provides the medical service) (Dahlui and Aziz 2012).

The private health sector is the second major provider of health services, through their private hospitals and clinics (Merican et al. 2004). The private health sector in Malaysia began operations four decades ago and can be divided into four main groups: private practitioners, private hospitals, private non-governmental organizations, and practitioners of traditional medicine. This sector has been on the rise, especially in urban areas. The types of private health care services include private hospitals, maternity homes, nursing homes, hospices, ambulatory care centres, haemodialysis centres, community mental health centres, medical clinics, and dental clinics. In 2011, there were 220 private hospitals (with a total 13,568 beds), 25 maternity homes, 14 nursing homes, four hospices, 46 ambulatory care centres, 344 haemodialysis centres, 6,589 medical clinics and 1,576 dental clinics (Ministry of Health Malaysia 2012b). Table 1.2 shows the various types of health facilities in the Malaysian healthcare system offered by the private health sector.

In addition, some non-governmental organisations, such as the professional and civic associations as well as societies, have also contributed towards the provision of health care in the country. Most of these non-governmental organisations complement the tasks undertaken by the Ministry of Health Malaysia especially in areas that are not covered by the ministry. For example, non-governmental organisations play a major role through providing community care for the elderly, the mentally ill, and the mentally and physically challenged (Merican et al. 2004).

As mentioned previously, the Malaysian public healthcare system is highly subsidised by the government, and patients are charged a minimum or no fee when they seek medical treatments at the primary, secondary, and tertiary healthcare facilities (Nik Rosnah 2005). Starting from the year 2006, all Malaysian citizens aged 60 years and above are exempted from registration and consultation fees (usually MYR 1 (equivalent to GB 6.5 in 2015) for primary health care clinics and it costs MYR5 (£32.50) for each outpatient visit at all public primary health care and hospital clinics. These fees include fees for medical consultations, investigations, and drugs medication (Ministry of Health Malaysia 2008a).

In contrast with public health sector, the private sector imposes fees on patients for utilizing health services in order to operate and maintain their facilities. Payments for services in the private sector are funded mainly by patients' out-of-pocket payments, employer-provided insurance with panel doctors, and private medical insurance (Ministry of Health Malaysia 2008a).

Currently in Malaysia, NCDs are becoming the main diseases affecting the Malaysian community, with diabetes mellitus being one of the main diseases. In the year 2000, diabetes mellitus was estimated to be the seventh leading cause of burden of disease in Malaysia, accounting for 3.7% of total disability-adjusted life years (Yusuff et al. 2005). In line with these findings, Malaysia has already implemented a number of health campaigns, as well as placing the emphasis on a new set of goals in the 10th Malaysian Plan (2011-2015). One of the strategic thrusts of the 10th Malaysian Plan was to transform the healthcare system in Malaysia by providing easy healthcare access and fostering disease prevention.

Table 1. 1 Healthcare facilities in Malaysia health system (Government)

Government		
Ministry of Health	No	Beds (official)
Hospitals	138	38,394
- Hospitals	132	33,812
- Special Medical Institutions[1]	6	4,582
Dental Clinics		
- Dental Clinics[2]	51	459[3]
- Mobile Dental Clinics	27	27[3]
Health Clinics		
- Health Clinics[4]	985	-
- Community Clinics (K.Desa)	1,864	-
- Mobile Health Clinics (Teams)	-	184[5]
- Flying Doctor Services (Teams)	5[6]	12[5]
1Malaysia Clinics		
- 1 Malaysia Health Clinics	109	-
- 1 Malaysia Mobile Clinics (Bus)	5	8[5]
- 1 Malaysia Mobile Clinics (Boat)	1	2[5]
Non Ministry of Health		
Hospitals	8	3,322

[1] Refers to 1 Leprosy, 1 Respiratory and 4 Psychiatrics Institutions
[2] Refers to Standalone Dental Clinics
[3] Refers to Dental Chairs
[4] Health Clinics include Maternal & Child Health Clinics
[5] Refers to Teams
[6] Refers to Helicopters

Table 1. 2 Healthcare facilities in Malaysia health system (Private)

Private		
Licensed	No	Beds (official)
Hospitals	220	13, 568
Maternity Homes	25	105
Nursing Homes	14	362
Hospice	4	38
Ambulatory Care Centre	46	125
Blood Bank	5[a]	25[b]
Haemodialysis Centre	344	3,113[c]
Community Mental Health Centre	1	9
Combined Facilities[1]	1	14
Registered		
Medical Clinics	6,589	-
Dental Clinics	1,576	-

[1] Ambulatory Care and Haemodydialysis Centre
[a] Refers to 4 Cord Blood Stem Cells and 1 Stem Cells and Regenerative Medicine Research Lab and Services
[b] Refers to banks/tanks
[c] Refers to dialysis chairs

1.8 Healthcare services related to diabetic foot ulcer patients in Malaysia

Generally in Malaysia, diabetes care is mainly provided within healthcare facilities, including in the primary care and secondary care settings. The Ministry of Health Malaysia started a special programme for diabetes in 2000 called "The National Diabetes Prevention and Control Programme" in order to prevent and control diabetes. The National Diabetes Prevention and Control Programme comprises three levels, namely, primary prevention, secondary prevention, and tertiary prevention (Ministry of Health Malaysia 2010). As stated in the Malaysian Health Report and Malaysian National Strategic Plan for NCD (Ministry of Health Malaysia 2008a; Ministry of Health Malaysia 2010), the management of diabetes between primary care and secondary care settings may differ accordingly.

Primary prevention usually involves health promotion programmes, which address the main risk factors for diabetes, such as unhealthy eating, physical inactivity, and obesity. In addition, primary prevention also aims to increase community awareness of cardiovascular risks (Ministry of Health Malaysia 2010).

According to the Ministry of Health Malaysia (2010), secondary prevention of diabetes in Malaysia is implemented through a combination of pharmacotherapy

and behavioural modification programmes; these are implemented in primary care and secondary care settings respectively.

Meanwhile, tertiary prevention is mainly implemented in secondary and tertiary care settings, as it usually requires monitoring from specialists and collaborative management. The activities carried out in the tertiary prevention of diabetes in Malaysia include regular physical assessments and screening for diabetes complications as well as treatment of specific diabetes complications (Ministry of Health Malaysia 2010).

In the primary health care clinics, diabetes care is managed by family physicians and medical and health officers; they are supported by nurses and nutritionists who specialise in the treatment of diabetes. The usual diabetes care provided in primary health care clinics focuses on primary and part of secondary prevention, with an emphasis on education for people who are identified as being at risk of developing diabetes, in order to prevent and minimise the incidence of diabetes (Ministry of Health Malaysia 2009; Ministry of Health Malaysia 2010). In the primary health care clinics, diabetes patients normally visit the clinic every three or four months. In some cases, patients are seen at more frequent intervals depending on their condition and disease control. Apart from that, cardiovascular disease control surveillance is conducted annually. The diabetes patients receive care from medical and health officers. They will be seen by family physicians only if the diabetes becomes out of control or if they develop complications. Moreover, diabetes patients receive health education on a healthy diet and dietary prescriptions from nutritionists who visit the primary health care clinics at a monthly interval. For diabetes patients who have developed foot ulcers, wound care such as wound dressing is provided by nurses and medical assistants. It is a common practice for diabetes patients to visit the clinic for wound dressing every day or at given intervals depending on their wound condition. If the patients have several complications, such as wet gangrene, infected wounds, and abscesses, they are referred to secondary care or tertiary care settings for further investigation and for treatment by the wound management team.

The diabetes management in the secondary care settings differs from that of the primary care settings. In the secondary care settings, diabetes management

is focused on secondary and tertiary prevention, as reflected by the function of the hospitals, which focus more on acute care and curative approaches. Therefore, their practices are dedicated more to treatment and care. In contrast, the primary care clinics accept walk-in patients, while secondary care clinics commonly receive patients from referrals. Patients are commonly referred to the hospital from primary care clinics, private practitioners, or in the case of follow ups for patients discharged from wards or other hospitals. Access to secondary care is usually initiated by the specialists or the primary care team when the patient seeks diabetes care. The diabetes care team in the secondary care clinics comprises internal medicine physicians or an endocrinologist, medical officers, a diabetes nurse educator, nurses, pharmacists, and dieticians. In a secondary care setting, diabetes patients are seen by a doctor every three months or at an interval that is established depending on their disease control. The diabetes patients with diabetic foot ulcers are referred to the wound management team for wound care. Similar to those in primary care clinics, diabetes patients with foot ulcers in a secondary care clinic will visit the clinic for wound dressing every day, every alternate day, once a week, or depending on their wound condition.

Nurses are the key persons in the management of diabetic foot ulcers. In Malaysia, they are responsible for both establishing a treatment plan and for carrying out the treatment in the vast majority of cases of diabetic foot ulcers. The wound-care specialists or physicians also play a significant role in establishing a treatment plan.

Although the orientation of diabetes management may differ, *Clinical Practice Guidelines for Management of Diabetes Mellitus Type 2* (Ministry of Health Malaysia 2009) were developed to guide and assist in the management of diabetes patients. At the same time, *Clinical Practice Guidelines for Management of Diabetic Foot Disorders*, which was published in 2004, acts as the reference to identify diabetic patients who are at risk of foot complications and as a guide for the management of Malaysian diabetic patients with foot disorders (Ministry of Health Malaysia 2004).

These guidelines are generally used in primary and secondary care settings. Furthermore, these guidelines are regularly reviewed and updated using the latest evidence available.

1.9 Statement of the problem

In 2011, the reported prevalence of diabetes mellitus in Malaysia was at 15.2% (NHMS 2011). It is estimated that 15% to 20% of these diabetics will be hospitalized with foot complications at some time during the course of their disease, and 12%-24% of the affected individuals with foot ulcers will require amputation (Muhammad Anwar Hau 2008).

Chronic wounds, such as venous ulcers, ischemic ulcers, pressure ulcers and diabetic foot ulcers, may cause debilitating pain. Although an extensive amount of literature exists on the nature of and treatments for chronic wound pain as a primary condition, little is known about the impact of chronic pain in diabetic foot ulcers. It can be argued that, traditionally, there has been a misconception that diabetic foot ulcers are not painful. Diabetic foot ulcer pain has been under investigation and is often overlooked due to the assumption that patient will experience less pain due to peripheral sensory neuropathy (Upton et al. 2013). Sibbald et al. (2003) and Woo (2010) highlighted that a person with diabetes mellitus may experience pain as a result of neuropathy; the onset of limb-threatening complications, such as deep infection or a deep disruption of the bony structure due to Charcot changes; or critical ischemia. However, recently, a growing body of evidence has refuted this view by demonstrating that a significant number of participants with diabetic foot ulcers report moderate to severe pain. Quality of life studies have consistently highlighted that for participants living with a diabetic foot ulcer, pain is an overwhelming issue which profoundly affects their lives (Ribu et al. 2006). In recent research by Bradbury and Price (2011a) and Bradbury and Price (2011c [phase 1]) 28 participants with diabetic foot ulcers were examined. Of these, 86 per cent (n=24) reported some degree of diabetic foot ulcer pain and confirmed that pain affected their quality of life particularly the physical and psychological aspects.

Although the above studies have provided useful information on the condition, where literature on patient outcomes was otherwise sparse, the authors have

acknowledged that there are certain issues with the results. Sample sizes for both studies were relatively small (n = 127 in (Ribu et al. 2006 and n = 28 in Bradbury and Price 2011a; Bradbury and Price 2011c). Bradbury and Price (2011a) and Bradbury and Price (2011c) recruited patients from only one diabetic clinic while Ribu et al. (2006) recruited their patients from a hospital-based diabetic outpatient clinic only; therefore, the findings may exhibit poor external validity. Even though the study by Ribu et al. (2006) acknowledged diabetic foot ulcer pain to be important, no formal assessment was performed, as the primary aim of the study was not to evaluate the specifics of diabetic foot ulcer pain. Furthermore, in the studies by Bradbury and Price (2011a; 2011c), limited inferential statistics were applied due to the sample size, which was considered to be too small to provide valid detailed information on the relationship between pain sensations with other variables.

To strengthen the notion further, Woo et al. (2008) also suggested that the experience of living with a chronic wound has a huge impact on a diabetic patient's quality of life, and pain is one of the symptoms that participants find particularly distressing. As a result, it can lead to delayed healing of acute and chronic wounds while, at the same time, reducing a patient's immune response, resulting in an increased risk of infection (Cole-King and Harding 2001).

To date, there is only one published study regarding the health-related quality of life of patients with diabetic foot ulcers in Malaysia, and the results have shown that diabetic foot problems have negative impacts on participants' health-related quality of life in both physical and mental health aspects (Mazlina et al. 2010). Although there is a significant link between bodily pain and physical functioning amongst these participants, no detailed discussion is provided, as the scope of the study did not allow for exploration of the cause of that pain and its impacts on a patient's functional status. The current study has also utilised the medical outcome study short-form 36- item health survey (SF-36) as its measurement tool, which is not a disease-specific tool for diabetes-related foot problems.

Despite these consistent findings, the available literature has very limited information on the sample, scope and methodology of the studies. General conclusions have been limited by several factors. First of all, the majority of the research is based on small, consecutive samples from a diabetic foot clinic and

therefore, findings may not be generalized to the wider diabetic foot ulcer population. Secondly, in terms of the method of pain assessment, some of the researchers have failed to use the standardized pain assessment tools which are commonly used in the literature about pain. Finally, the level of statistical analysis was more often than not at the univariate or bivariate level. To the researcher's best knowledge, there was no study that utilised multiple linear regression to examine complex relationships and to control for the likely confounding variables.

1.10 Aim and objectives of the study

The aim of the current study is to investigate the relationships between diabetic foot ulcer pain and health-related quality of life and functional status in people over sixty years in Malaysia. In particular, the specific objectives together with the research questions to be addressed are as follows:

1. To measure the pain experiences in people over sixty years with diabetic foot ulcers in Malaysia.

- What are the pain experiences by people over sixty years with diabetic foot ulcers in Malaysia?
- What are the similarities and differences in the pain experiences between people over sixty years in Clinic S and Clinic P?

2. To measure the health-related quality of life of people over sixty years with diabetic foot ulcers in Malaysia.

- What is the health-related quality of life of people over sixty years with diabetic foot ulcers in Malaysia?
- What are the similarities and differences in the health-related quality of life between people over sixty years in Clinic S and Clinic P?

3. To measure the functional status of people over sixty years with diabetic foot ulcers in Malaysia.

- What is the functional status of people over sixty years with diabetic foot ulcers in Malaysia?

- What are the similarities and differences in the functional status between people over sixty years in Clinic S and Clinic P?

4. To investigate the relationships between pain and the selected socio-demographic and clinical characteristics, the health-related quality of life, and the functional status of people over sixty years with diabetic foot ulcers in Malaysia.

- What are the relationships between pain and the selected socio-demographic characteristic (age categories, gender, race, religion, marital status, level of education, and number of additional floors in the house), the selected clinical characteristic (duration of diabetes mellitus, number of co-morbidities, duration of foot ulcer episode, number of foot ulcer episode, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution, and type of dressing), the health-related quality of life, and the functional status of people over sixty years with diabetic foot ulcers in Malaysia?
- What are the similarities and differences in relationship between the selected socio-demographic characteristics (age categories, gender, race, religion, marital status, level of education and number of additional floors), selected clinical characteristics (duration of diabetes mellitus, number of comorbidities, duration of foot ulcer episode, number of foot-ulcer episode, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution, type of dressing), the health-related quality of life and the functional status between people over sixty years in Clinic S and Clinic P?

5. To investigate the predictors of pain in people over sixty years with diabetic foot ulcers in Malaysia.

- What are the predictors of pain among Malaysian people over sixty years with diabetic foot ulcers?

6. To examine the health care clinic use by people over sixty years with diabetic foot ulcers in Malaysia.

- How do people over sixty years with diabetic foot ulcers in Malaysia use the health care clinic?

- How do people over sixty years in Clinic S and Clinic P use the health care clinic?

1.11 The significance of the study

The current study gives some potential benefits to the following parties such as the following.

1.11.1 Nurses

The study will provide information on diabetic foot ulcer pain and its relationships with health related quality of life and functional status among people over sixty years. Since diabetic foot ulcer pain is often overlooked, it is hoped that the findings from the current study will increase the awareness and understanding of diabetic foot ulcer pain, thus helping the nurses to understand the reason why diabetic foot ulcer patients experience wound-related pain. This will help in the decision-making process by nurses on the appropriate healthcare plan for their patients, such as to develop and deliver an individualized care catering to the patient's need to reduce discomfort and increase the patient's quality of life. This will also facilitate the multidisciplinary team involved in the management of diabetic foot ulcer patients to have a better understanding of patients seeking treatment for their illnesses. Furthermore, an awareness of diabetic foot ulcer pain will help to promote health and meet patients' health needs.

Most studies of diabetic foot ulcer pain and its relationships with health-related quality of life have been conducted in Western countries. The result of such research may have limited relevance to the Malaysian context especially in nursing practice. Therefore, nurses in Malaysia will be able to utilize findings from the current study in Malaysia's health care practice. It is also important that the current study will stimulate future research development in this area.

1.11.2 Patient

It has been well documented in the literature that pain is a common problem in chronic wounds (pressure ulcer, venous ulcer and ischemic ulcer). Similar to

other chronic wounds, diabetic foot ulcers are also known to be painful. As mentioned previously, diabetic foot ulcer pain has negative impacts on an individual's health-related quality of life and functional status especially in older people. Therefore, by exploring the meaning of diabetic foot ulcer pain from the patients' perspectives, it is hoped that the findings will aid in maintaining the best possible health status and level of functioning in order to improve patients' quality of life.

1.11.3. Organization

The management of older people with diabetic foot ulcers has a huge impact on health care systems as, due to the growing number of patients with diabetic foot ulcers, there will be an increase in the number of patients requiring care of diabetic foot ulcer pain. This scenario will potentially lead to increased health-care costs. Therefore, the results of the study would create awareness of diabetic foot ulcer pain and its relationships with health-related quality of life and functional status. Having acknowledged this, manage more effectively will result in a shorter length of hospitalization, thus reducing the cost of health care and finally, benefitting the organization.

Furthermore, organizations are also expected to conduct courses related to diabetic foot ulcers and pain in order to increase the level of knowledge amongst their staff in giving health education or counselling in regard to pain management particularly in diabetic foot ulcer pain.

The findings from the current study can also be used to initiate a public and private hospital partnership to disseminate the knowledge to both patients and the caregivers on diabetic foot ulcer pain, which will have a great impact on their health-related quality of life and functional status.

1.11.4 Researcher

The findings from the current study are very important to the researcher herself as a nursing lecturer. Nurses' knowledge and understanding of diabetic foot ulcer pain amongst older people are important in order to enhance their health, functions, and quality of life. Unfortunately, most nurses nowadays have the

wrong perception by believing that patients with diabetic foot ulcers will not experience pain due to peripheral sensory neuropathy. Therefore, the results from the current study would add to the body of knowledge in the field of pain management among nurses in Malaysia. After the study, the researcher, in collaboration with the nursing education service, will be able to offer continuous nursing education to those nurses who focus on training and education on diabetic foot ulcer pain in order to improve nurses' awareness and knowledge as well as enabling them to disseminate the knowledge to patients and their families.

1.12 Definition of terms

Diabetes mellitus

Diabetes mellitus is a group of chronic metabolic conditions, which are characterized by elevated blood glucose levels resulting from the body's inability to produce insulin, its resistance to insulin action, or both (American Diabetes Association (ADA) 2006).

Diabetic foot ulcer

Diabetic foot ulcers are full-thickness penetration of the dermis of the foot in a person with diabetes (Hunt 2011).

Pain

Pain is defined as an "unpleasant sensory and emotional experience caused by real or potential injury or damage to the body" (International Association for the Study of Pain 1999).

Health-related quality of life

Health-related quality of life is a multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning. It goes beyond direct measures of population health, life expectancy, and causes of death, and focuses on the impact health status has on quality of life (Centres for Disease Control and Prevention (CDC) 2000).

Functional status

Functional status is an individual's ability to perform the normal daily activities required to meet basic needs, play their usual roles, and maintain health and well-being (Leidy 1994).

Older people

According to the definition by the United Nations, older people usually means people aged 60 or 65 years old and above. A number of academic papers have adopted the definition that older people are those aged 65 and above when conducting studies on developed countries such as Australia, the United Kingdom, and the United States, and consider older people as those aged 60 when looking at developing countries such as Indonesia, Thailand, and Malaysia. In this research, the term ‘older population’ is used to refer to persons aged 60 and above, as it is stated in the government policy that Malaysians are eligible for old age benefits, such as the pensioner scheme, when they are 60 or over (Department of Social Welfare Malaysia 2012).

Wagner wound classification (Wagner 1981)

The classification of foot ulcers has been developed and used for planning treatment, monitoring its effectiveness, predicting clinical outcomes, and improving communication among health care professionals (Armstrong et al. 1998). In the current study, diabetic foot ulcers have been classified using the commonly used Wagner wound classification (Ministry of Health Malaysia 2004). The Wagner wound classification is a perfectly usable instrument in clinical practice (Acker et al. 2002). The wound classification was made according to the depth of the ulcer, the degree of infection, and the presence or absence of gangrene and its extent (Oyibo et al. 2001). The Wagner ulcer classification system is shown in Table 1.3.

Table 1. 3 Wagner wound classification (Wagner 1981)

Grade	Features
0	Pre-ulcer. No open lesion. May have deformities, erythematous areas of pressure or hyperkeratosis.
1	Superficial ulcer. Disruption of skin without penetration of subcutaneous fat layer.
2	Full thickness ulcer. Penetrates through fat to tendon or joint capsule without deep abscess or osteomyelitis.
3	Deep ulcer with abscess, osteomyelitis or joint sepsis. It includes deep plantar space infections, abscesses, necrotizing fascitis and tendon sheath infections.
4	Gangrene of a geographical portion of the foot such as toes, forefoot, or heel.
5	Gangrene or necrosis of large portion of the foot requiring major limb amputation.

Dermacyn

This product can be used for moistening absorbent wound dressings and for debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, and abrasions and minor irritations of the skin.

Ingredients: Oxidized water 99.97%, Sodium Chloride (NaCl) 0.023%, Sodium Hypochlorite (NaOCl) 0.023%, Sodium Hypochlorous Acid (HOCl) 0.003% (Oculus Innovative Sciences 2015)

Prontosan

This product can be used for cleansing, rehydrating, and decontaminating acute and chronic wounds that are at risk of infection by aiding the removal of bacteria and debris and disrupting biofilm. Prontosan can be used in acute and chronic wounds, such as surgical and traumatic wounds, leg ulcers, pressure ulcers, diabetic foot ulcers, and first and second degree burns.

Ingredients: Purified water, polyhexamethylene biguanide 0.1%, betaine (a surfactant) 0.1% (Bradbury and Fletcher 2011)

Hydrocyn

This product can be used for wound cleansing, such as pressure ulcers, burns, diabetic foot ulcers, wound irrigation, and general hygiene.

Ingredients: Electro Activated Super-Oxidized Water 99.9%, Hypochlorous Acid (HOCl) 0.03%, Hypochlorite (NaOCl) 0.03%, Sodium Chloride (NaCl) 0.04% (Vigilenz 2015)

1.13 The structure of the thesis

The thesis is divided into seven chapters.

Chapter 1

Chapter one introduces the background information to the research project, the problem statement of the study, the aims, the research objectives, and the research questions. The significance of the study, the definitions of some key terms, and the description of the thesis structure also form part of this chapter.

Chapter 2

This chapter is presented in two sections. Section 1 discusses the concept of pain, as well as types of wound pain and their physiology, and provides an overview of the theories of pain. Section 2 discusses the process and findings from the literature review that highlighted the gap in knowledge and practice that justified the relevance of the current study.

Chapter 3

This chapter describes the research design and the methods used to conduct the study as well as the translation process for the questionnaire. Finally, ethical approval, ethical considerations, and the data analysis process are also described in Chapter 3.

Chapter 4

This chapter presents the reliability and validity of the scales used in the study. It also discusses the characteristics of the participants, their pain level, health-related quality of life, functional status, and health care use. This chapter also presents pain and its associated factors using bivariate analysis. Finally,

predictors of pain using stepwise multiple linear regression analysis are also presented in this chapter.

Chapter 5

This chapter presents the findings in terms of the similarities and differences between Clinic S (secondary care clinics) and Clinic P (primary care clinics) regarding the relationships between pain and health-related quality of life and functional status.

Chapter 6

This chapter discusses the main findings in answering the research questions. Section 1 discusses participants' characteristics. Section 2 discusses the pain, health-related quality of life, and functional status of people over sixty years with diabetic foot ulcers in Malaysia. Section 3 discusses the relationships between diabetic foot ulcer pain and socio-demographic factors, clinical variables, health-related quality of life, as well as functional status. Section 4 discusses the predictors of diabetic foot ulcer pain. Finally, the way people over sixty years with diabetic foot ulcers use health care clinic is also discussed in this chapter.

Chapter 7

The final chapter presents the originality and contributions of the study. The strengths and limitations of the study are also acknowledged. Recommendations and the implications of the findings are also stated in this chapter.

1.14 Summary

Diabetic foot ulcer-related pain is a significant problem which has long been under investigated and is currently poorly understood. Where available, empirical data are often limited by methodological and analytical problems such that substantive conclusions about the scope and nature of diabetic foot ulcer-related pain remain unclear. Little is known about how pain contributes to diabetic foot ulcer related health-related quality of life and functional status. It is clear that there are substantial gaps in the literature and that many basic

questions about the scope, characteristics, and impacts of pain problems among individuals with diabetic foot ulcers remain unanswered.

To the researcher's best knowledge, to date, there are no data available on diabetic foot ulcer pain, and research from other countries could not be generalised to describe that of the local population. Therefore, with an increasing older population in Malaysia and because diabetic foot ulcer pain is a particular area which has been under-researched, it is vitally important that this problem is acknowledged. It is hoped that the current study will provide additional data on this issue. This data will be beneficial in designing a better health care program for older patients with diabetes.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter is presented in two sections. Section 1 discusses the concept of pain, types of wound pain, and the physiology of pain. It also provides an overview of the theories of pain.

Section 2 presents the search strategy used to find relevant studies. It also analyses and discusses the literature related to diabetic foot ulcer pain and its relationships with patients' health-related quality of life and functional status.

2.2 Concept of pain

Pain has been variously defined in previous studies, but the most consistently adopted definition is the one provided by the International Association for the Study of Pain (IASP). IASP defines pain as "an unpleasant sensory or emotional experience associated with actual or potential tissue damage or described in terms of such damage or both" (IASP 1999). This definition indicates that pain can be physiological and psychological. These two factors should be considered by nurses when assessing patients with tissue damage.

2.3 Types of wound pain and its physiology

Wound pain is complex and is usually an unpleasant sensation that is unique to each individual. Pain is often described as either nociceptive or neuropathic in terms of its origin. Nociceptive pain is defined as "an inflammatory response to tissue damage with an identified trigger or stimulus" (Reddy et al. 2003, p.2). The pain tends to be relatively acute. Neuropathic pain, on the other hand, is spontaneous and not stimulus dependent; it is caused by injury to the peripheral or central nervous system and therefore is usually chronic (Hanpaa and Treede 2010). The descriptors of both these types of pain tend to differ; nociceptive pain is often described as aching or throbbing whereas neuropathic pain is often

described as burning, shooting, or stabbing. As chronic wounds often involve both soft tissue damage and damage to nerve endings, it is not unusual for patients to report both types of pain (Doughty 2006).

The first model for the assessment and treatment of chronic wound pain was presented by Krasner in 1995 (Krasner 1995). This model is useful for categorising pain and recognising pain experiences. Krasner (1995) classified wound pain into three categories: chronic or persistent wound pain, cyclic acute wound pain, and noncyclic wound pain. Chronic or persistent wound pain is described as a background symptom that exists at rest and between wound-related procedures or dressing changes. Cyclic acute wound pain is induced by recurring treatment interventions, such as regular dressing change, and noncyclic acute wound pain occurs as a one-time procedure, such as sharp debridement.

Pain is a common experience for patients with wounds. Wound pain may be caused by skin damage, nerve damage, blood vessel injury, infection, and ischaemia (Mudge and Orsted 2010; Frescos 2011). Dressing changes and removal, cleansing, debridement, or compression therapy have also been reported to contribute to wound pain (Mudge and Orsted 2010).

Pain occurs in response to tissue damage or to direct noxious stimulus such as mechanical (touch or pressure) or thermal (hot or cold) factors. This noxious stimulus is then transmitted by primary afferent nerve fibres to the dorsal horn of the spinal cord before reaching the brain for interpretation. Pain is characterised by two types of nociceptors: unmyelinated C and myelinated A-fibres. Many unmyelinated C-fibres are polymodal, while some become active only during tissue inflammation (Wulf and Baron 2002). Unmyelinated C-fibre nociceptors remain silent until they are activated by either direct injury or inflammation. When this occurs, the nociceptors release pain and inflammatory mediators, which decrease nerve-fibre firing thresholds and increase the sensitivity of the unmyelinated C and myelinated A-fibres. The increase in neuron sensitivity to repeated stimulation can lead to small stimuli being perceived as very painful (hyperalgesia) (Wulf and Baron 2002).

2.4 Theories of pain

Three pain theories are proposed to help understand pain: specificity theory, the gate control theory, and the biopsychosocial pain model.

The specificity theory

The specificity theory was introduced by Renè Descartes in 1644 (Melzack and Wall 1987). This theory proposes that a pain pathway is a straight channel that carries pain from designated pain receptors from the skin to a pain centre in the brain (Melzack and Wall 2008). The theory, however, ignores the influence of psychological and social factors on the pain experience (Melzack and Wall 2008), thus it would not provide a full explanation of the relationships between diabetic foot ulcer pain and health-related quality of life and functional status.

The gate control theory

The gate control theory was introduced by Melzack and Wall in 1965 (Melzack 1999). The theory is well recognised and widely accepted in studies of pain. The gate control theory of pain emphasises the potential role of psychological factors in the perception of pain (Melzack and Wall 2008). Psychological aspects, such as thoughts, feelings, and emotions, can influence the opening or closing of the gating mechanism and thus, influence the pain experience. Because the experience of pain involves the central and peripheral nervous systems, it depends on how the two systems process pain signals. When an injury occurs, the pain message is transmitted via the peripheral pathways to the spinal cord, which carries the message to the brain.

The gate control theory proposes that before the message can reach the brain, it encounters nerve gates in the spinal cord. If the nerve gates are open, then the message is transmitted to the brain, and the pain experience is felt. If the nerve gates are closed, then the pain message is prevented from reaching the brain (Melzack and Wall 1999). However, the gate control theory does not clarify how the brain processes pain perception, and there are multiple factors inside and outside the human body system that might influence the pain. Therefore, the gate control theory would not provide a full explanation of the

relationships between diabetic foot ulcer pain and health-related quality of life and functional status.

The biopsychosocial model

The biopsychosocial model was developed by George L. Engel in 1977 (Engel 1977). The theory was developed following the inability of the traditional biomedical model (which solely clarifies a biomedical component) to explain the influence of social, psychological, and behavioural factors on an individual's belief and behaviour in relation to health and illness (Engel 1977).

The biopsychosocial model of pain was chosen in this study because it illustrates the most relevant concepts that can explain diabetic foot ulcer pain (see Figure 2.1). This model proposes that the experience of pain is determined by the interaction among biological, psychological, and social factors in influencing a person's perception of, and response to, physical signs and symptoms.

The first domain of the biopsychosocial model is biological factors, which refers to tissue damage, genetic factors, and endogenous pain inhibition. The second domain is psychological factors, which refers to anxiety, depression, coping strategies, and social learning. The third domain is social factors, which refers to ethnicity, family history, and cultural factors. Nowadays, the biopsychosocial model has been greatly accepted and widely used as the most relevant approach in managing chronic pain (Gatchel et al. 2007).

In the case of diabetic foot ulcers, the element of biological factors refers to the pain itself. The pain arises from neuropathy due to injury or trauma, which causes nerve damage in the central nervous system (Upton 2014). Patients with neuropathic pain mostly describe the pain as burning, stabbing, sharp, and a sensation that resembles electric shocks and pin pricks (Woo et al. 2013). In addition, the pain mechanism associated with diabetic foot ulcers is also categorised as nociceptive pain, which occurs when receptors sense and respond to parts of the body that suffer from damage or trauma (Upton 2014). The pain can be caused by the interventions carried out during the course of treatment, such as dressing changes and removal, cleansing, debridement, or compression therapy (Mudge and Orsted 2010). An international survey by

Price et al. (2008) revealed that more than 62% of the participants had experienced pain for up to two hours after dressing procedures. The nociceptive pain is often described as sharp, aching, throbbing, or gnawing (Woo et al. 2013).

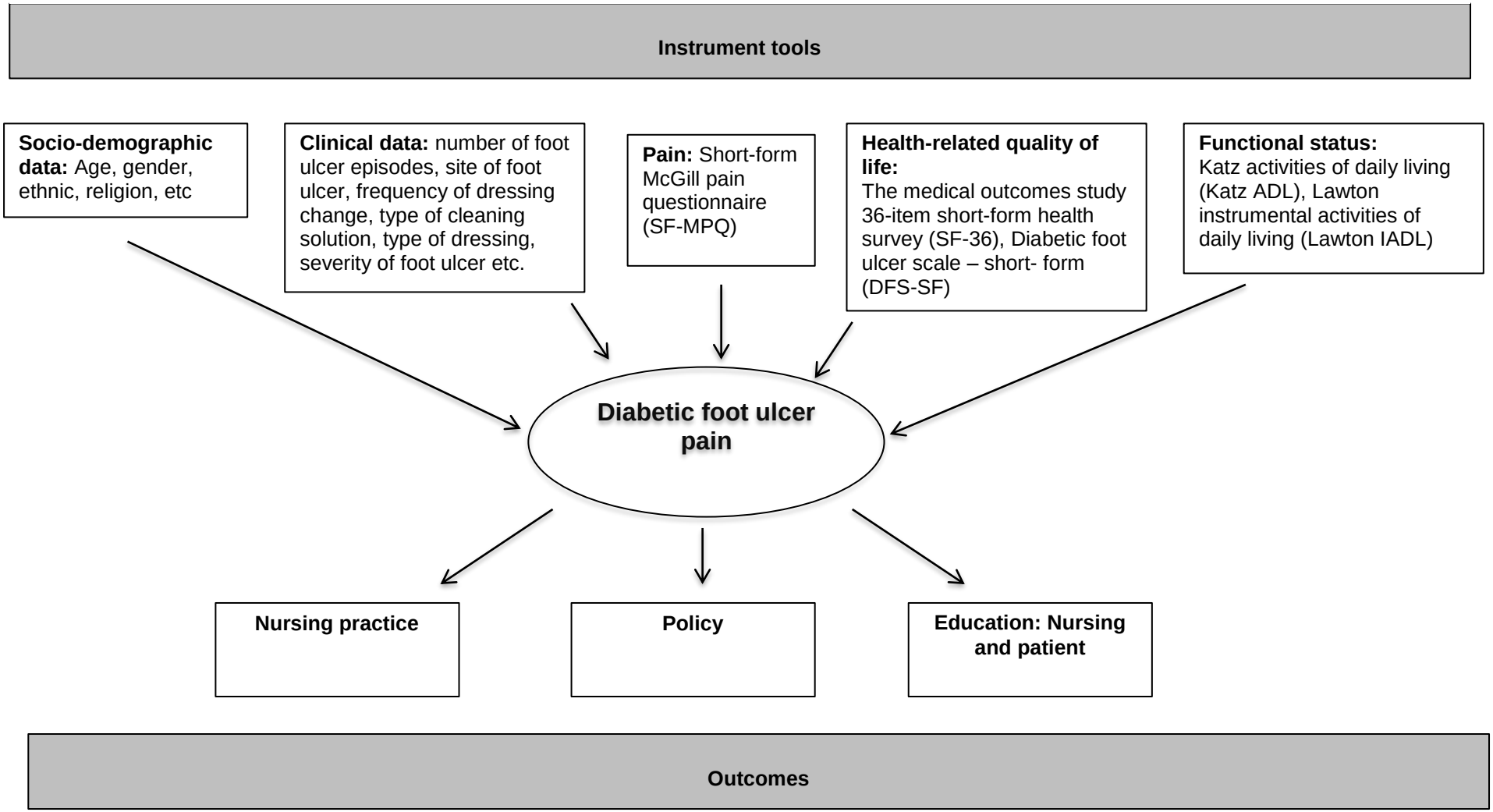
When pain is present, people tend to react towards it. Psychological factors, such as depression, anxiety, and anger, may influence a patient's health-related quality of life. In this study, the SF-36, the diabetic foot ulcer scale short-form (DFS-SF), Katz activities of daily living (Katz ADL) and Lawton instrumental activities of daily living (Lawton IADL) are evaluated among older patients with diabetic foot ulcers. It is expected that older patients with diabetic foot ulcers who are in pain may believe that mobility or physical activities might increase their pain (Ashford et al. 2000; Ribu and Wahl 2004; Ribu et al. 2006; Bengtsson et al. 2008: Bradbury and Price 2011b, Bradbury and Price 2011c [phase 2]). For this reason, they tend to avoid or minimise their movements or any physical activities to overcome their pain problems.

The accounts of pain can cause increased dependence on others for assistance with daily functional activities, such as showering, eating, and housework (Ribu and Wahl 2004; Watson-Miller 2006; Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]). Pain can also restrict participation in social activities, such as going outdoors, or involvement in sport activities. These limitations promote the feelings of loss of control and loss of self. Shortcomings may also develop the disability in older patients, which can leave them anxious and depressed. Furthermore, people in pain may attempt to isolate themselves from family and community.

This biopsychosocial model is claimed to be the most complete because any model that does not include any one of the elements is considered incomplete (Gatchel et al. 2007). The model is well integrated in explaining the interaction between biological, psychological, and social factors in diabetic foot ulcer pain.

The next section provides a critical review of the previous studies on pain in individuals with diabetic foot ulcers.

Figure 2. 1 The revised biopsychosocial model of pain



2.5 Framework of literature search strategy

A framework by Richardson et al. (1995) was used to formulate the research questions for the study. The population or patient, intervention, comparison, and outcomes (PICO) (Richardson et al. 1995) framework was adopted to make the process of asking an answerable question easier as well as to develop and refine the research approach. This framework allows for the identification of the information needed to answer the questions as well as to translate the questions into searchable terms. The PICO framework was also selected to assist in refining the questions and to facilitate the research process. Posing the PICO question, as Glasper and Rees (2013) suggested, was found to be helpful in defining the focus of the literature search. The format of (PICO) questions used to guide the process of literature extraction is as follows:

P: Population or patient

I: Intervention

C: Comparison (optional)

O: Outcomes

For this research, the PICO question is represented by the following: *P*: diabetic foot ulcer patient, *I*: No intervention, *C*: No comparison, and *O*: 1) health-related quality of life, 2) functional status. Table 2.1 below illustrates how the PICO framework was utilised to assist in the formulation of the questions for this study.

Table 2. 1 PICO framework (Richardson et al. 1995) for literature review

Population	Diabetic foot ulcer patient
Intervention	No intervention
Comparison	No comparison
Outcomes	Pain, health-related quality of life, functional status

2.6 Research questions for literature review

The questions formulated for this literature review are as follows:

1. What is the pain measurement used for patients with diabetic foot ulcers?
2. What is the level of pain experienced by patients with diabetic foot ulcers?
3. What is the relationship between pain and health-related quality of life and functional status of patients with diabetic foot ulcers?
4. How does the wound care (dressing change, cleansing, and type of dressing) affect the pain for patients with diabetic foot ulcers?

2.7 Search strategies

An initial search of the Cochrane library was performed to determine if any systematic review had been conducted on the topic. However, no systematic reviews were found on this specific topic. Existing studies on this topic were searched from three main databases: MEDLINE (Ovid), the Cumulative Index of Nursing and the Allied Health Literature (CINAHL), and British Nursing Index (BNI).

1. *MEDLINE (Ovid)*. This database offers reliable, comprehensive coverage, depth, and sophisticated search features (Robert and Priest 2010).
2. *Cumulative Index of Nursing and Allied Health Literature (CINAHL)*. CINAHL is a comprehensive index to literature published worldwide (Glasper and Rees 2013). It is widely known as the most comprehensive and significant database supporting over four thousand journals and covering over eleven million citations dating back to 1996 (Lanoe 2002).
3. *British Nursing Index (BNI)*. According to Parahoo (2006), the BNI was formed by collaboration between three university libraries and the Royal College of Nursing. Covering over two hundred journals, the BNI is claimed to be the most current nursing database for the UK journals.

The next step after formulating the PICO question was to list all the terms required to search for the PICO elements. The study focuses on diabetic foot ulcers and their relationships with health-related quality of life and functional status. Based on this aim, the terms used in the search include “diabetic foot ulcer,” “foot ulcer,” “pain,” “quality of life,” “health-related quality of life,”

“wellness,” “well-being,” “activity daily living,” “functional status,” “antimicrobial dressing,” “gauze dressing,” “saline soaked dressing,” “foam dressing,” and “gel dressing.” The results of each category were then combined using the Boolean terms “AND” and “OR” to narrow down the search findings (see Appendix 1).

Apart from that, the literature search was very much focused on research published between January 2000 and July 2016 in order to provide the most recent and up-to-date evidence and state of knowledge about diabetic foot ulcer pain and its relationships with health-related quality of life as well as functional status. ZETOC alerts were set up following the initial search process so that newly published work by key authors and in key topic areas could be identified.

In maintaining the focus of the review, several inclusion and exclusion criteria were introduced. As this study focuses on adult populations, only studies that reported diabetic foot ulcers in adults aged ≥ 18 years were included. Initially, only articles concerning patients aged 65 years and above were reviewed, but the database search had also captured articles with participants in younger age groups. For this reason, all studies that included participants aged 18 years and above with diabetic foot ulcers were included. Due to cost and time limitations for translating the articles from other languages into English or Malay, this review included only studies that were written in either language. The inclusion and exclusion criteria that were used to limit the search are listed below.

Table 2. 2 Inclusion and exclusion criteria for literature review

Inclusion criteria	Exclusion criteria
Studies concerning diabetic foot ulcers and health-related quality of life	Studies reported as review paper
The report carried data on adults aged ≥ 18 years old	Studies concerning diabetic foot ulcers and health-related quality of life patients aged < 18 years old
The report was written in English or Malay	The report was not written in English or Malay

2.8 Findings of the search

A total of 749 articles were identified in the search. Of these, 693 were deemed unrelated to the study and were excluded from the study. 56 of the remaining articles were reviewed in full. The findings of the literature search are detailed in Figure 2.2. Of the 56 articles that were assessed; 29 were excluded because they were either duplicate articles or review papers, and they did not meet the

inclusion criteria. This further shortlisting resulted in 27 studies, which consisted of 23 quantitative studies and four qualitative studies. Six studies were found to be specific to pain and diabetic foot ulcers while the remaining were on diabetic foot ulcers and health-related quality of life. The results of the studies are reported in tabular form based on data extraction tables. The data were extracted using the following headings: author, year of publication, country, research aims, research design, and sampling method, measurements findings, and research limitations. Table 2.4 and Table 2.5 outline the summary of the studies selected.

2.9 Characteristics of reviewed studies

The empirical studies were conducted in various countries. Nine of the twenty-three papers were conducted in the United Kingdom and the others were conducted in Holland, the United States, Norway, France, Brazil, Spain, and Bermuda. Of the selected studies, only three were conducted in Asian countries: one in Iran, another in Taiwan, and another in Malaysia. Overall, it can be deduced that most of the studies were conducted within the western hemisphere including the United Kingdom, the United States, and several other European countries. Very few studies were found to have taken place in Asian settings. This shows the scarcity of information related to diabetic foot ulcer pain in South East Asia settings, including Malaysia (see Table 2.3).

Figure 2. 2 Flow diagram for literature search on diabetic foot ulcer pain

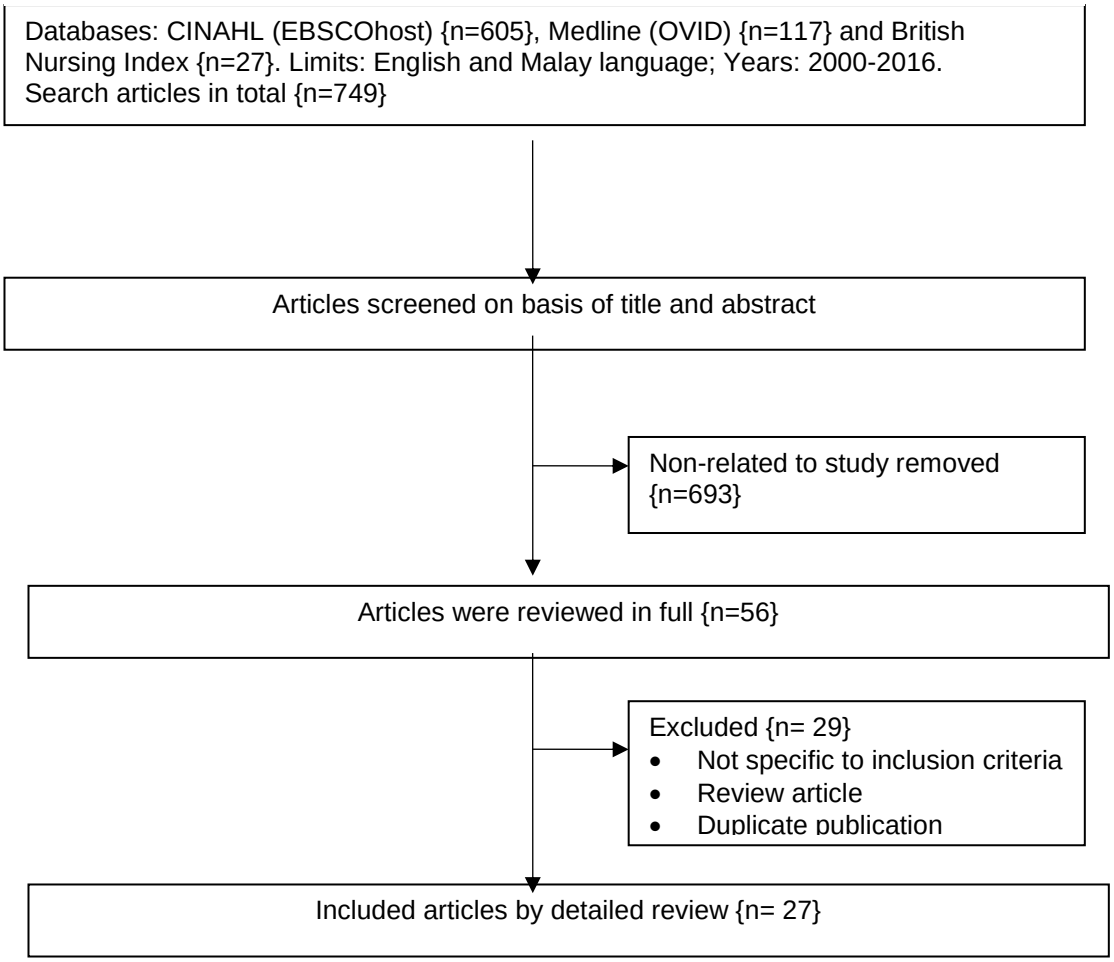


Table 2. 3 List of studies included in the review

Country where conducted	Authors	Year
Holland	Meijer et al.	2001
United States	Willrich et al.	2005
United States	Evans and Pinzur	2005
United Kingdom, United States and Europe	Nabuurs –Franssen et al.	2005
Norway	Ribu et al.	2006
United Kingdom	Goodridge et al.	2006
United Kingdom	Bengtsson et al.	2008
Norway	Ribu et al.	2007
France	Boutoille et al.	2008
United Kingdom	Winkley et al.	2009
United Kingdom	Yunus and Rajbhandari	2011
Norway	Jelsness-Jorgensen et al.	2011
Brazil	de Meneses et al.	2011
United Kingdom	Bradbury and Price	2011a
United Kingdom	Bradbury and Price	2011c
Spain	Morales et al	2011
Iran	Sanjari et al.	2011
Malaysia	Mazlina et al.	2011
United Kingdom	Bradbury et al.	2011
Canada	Sibbald et al.	2011
Taiwan	Huang et al.	2012
United Kingdom	Ashford et al.	2002
Norway	Ribu and Wahl	2004
Bermuda	Watson-Miller	2006
United Kingdom	Bradbury and Price	2011b
Europe	Siersma et al.	2013
Nigeria	Obilor and Adejumo	2014

2.8 Technique of critical appraisal

A total of 27 studies met the inclusion criteria and were included in this review. Many tools have been established for appraising literature critically. The tools were used to find relevant scientific evidence from the included studies to support the study design. In this study, the Critical Appraisal Skill Program (CASP), which was published by the Public Health Resources Unit, England (PHRU) (2007), was used to review the qualitative and quantitative studies. Each tool has its specific appraisal questions; thus, the validity, results, and the clinical relevance could be comprehensively considered and covered using the CASP tools.

2.10 Methodological limitations of reviewed papers

From the review, it was found that all 27 studies provided a clear statement of their research aims supported by background information relating to diabetic foot ulcers. The aims and type of approach are clearly stated within the abstract or introduction. However, some important methodological limitations were identified from the studies.

2.10.1 Quantitative studies

2.10.1.1 Research design

23 of the studies were carried out using a quantitative design. The quantitative design, as Lacey (2010) pointed out, is the simplest type of research, which involves collecting numerical data and analysing the results using statistical tests.

Most of the quantitative studies were cross-sectional studies that were conducted using a comparative approach. The purposes were mainly to evaluate two or more different groups of patients. In two of the studies, comparisons were made among three groups of patients. The samples were divided into three groups according to the following conditions: (1) patients with diabetic foot ulcers or active Charcot foot arthropathy, (2) patients with lower extremity amputation, and (3) patients with no foot ulcer (Willrich et al. 2005). In Ribu et al.'s (2007) study, the samples were assigned as follows: diabetic foot ulcer patients, diabetes mellitus patients, and nondiabetes patients. Seven of the reviewed studies compared the health-related quality of life between patients with diabetic foot ulcers and those without diabetic foot ulcers (Meijer et al. 2001; Willrich et al. 2005; Jelsness-Jørgensen et al. 2011; de Meneses et al. 2011; Morales et al. 2011; Mazlina et al. 2011; Sanjari et al. 2011). In one of the studies, the health-related quality of life in patients with healed diabetic foot ulcers was compared against that of those with unhealed diabetic foot ulcers (Goodridge et al. 2006). Seven of the studies have been were carried out using the cross-sectional studies that examined the pain or health-related quality of life in groups of only diabetic foot ulcer patients (Evans and Pinzur 2005; Ribu et al. 2006, Bengtsson et al. 2008; Bradbury and Price 2011a; Bradbury and

Price 2011c [phase 1]); Siersma et al. 2013; Obilor and Adejumo 2014). There was one retrospective case control study comparing the quality of life of diabetic amputees with a non-amputee group experiencing diabetic foot ulcers (Boutoille et al. 2008). There were also five other prospective studies. The other five prospective studies consisted of the following: one study examined the health-related quality of life of diabetic foot ulcers patients and their caregivers (Nabuurs-Franssen et al. 2005); the second study made a comparison with another study that compared the pain of diabetic peripheral neuropathy between patients with diabetic foot ulcers and diabetes patients (Yunus and Rajbhandari 2011); the third study was a comparison of another study that compared the health-related quality of life between patients with diabetic foot ulcers and those without diabetic foot ulcers (Morales et al. 2011); while two other studies explored the influence of diabetic foot ulcers on health-related quality of life (Winkley et al. 2009; Huang et al. 2012). Additionally, there is also a case series study (Bradbury et al. 2011) which focused on the effects of Silvercel non-adherent dressing on various types of wound. The last study reviewed was a randomised controlled trial which investigated the effects of a polyhexamethylene biguanide foam dressing and non-antimicrobial foam in chronic wound patients (Sibbald et al. 2011) (see Table 2.4).

In a cross-sectional comparative study, Meijer et al. (2001) compared the quality of life between diabetic patients with (former or present) foot ulcers and those without foot ulcers. 38 patients were recruited from the Diabetes Department of the Rehabilitation Centre in Beatrixoord. The patients' quality of life was assessed using the Research and Development 36-item form (RAND-36) (Hays et al. 1993). The patients' functional status and mobility were assessed using the Barthel Index Score (Mahoney and Barthel 1965) Walking and Walking Stairs Questionnaire (WWSQ) (see Table 2.4).

Willrich et al. (2005) sought to compare the health-related quality of life between patients with diabetic foot ulcers or active Charcot foot arthropathy and those with diabetes lower extremity amputation. The study had a sample of (1) 20 patients with diabetic foot ulcers or active Charcot foot arthropathy, (2) another 20 diabetic patients with lower extremity amputation, and (3) another 20 with controlled diabetes and no foot ulcer but with evidence of peripheral neuropathy as determined by their insensitivity towards the Semmes-Weinstein 5.07 (10

gm) monofilament. The measurement included the SF-36 (Ware and Sherbourne 1992) (see Table 2.4).

In another study, Goodridge et al. (2006) compared the health-related quality of life of patients with healed and unhealed ulcers. 57 patients with unhealed foot ulcers and 47 patients with healed foot ulcers were recruited from a diabetic foot specialist clinic in Canada. Telephone interviews were conducted using the medical outcomes survey short form 12 (SF-12) tool to determine the quality of life (Ware et al. 1996) for both groups of patients. The unhealed group also completed the Cardiff Wound Impact Schedule (CWIS) (Price and Harding 2004) (see Table 2.4).

Ribu et al. (2007) looked into a cross-sectional population of 127 patients in Norway with diabetic foot ulcers. The patients were being treated as outpatients. The patients' health-related quality of life was compared with the scores of 221 diabetics and 5,903 nondiabetics from a previously conducted nation-wide survey. The SF-36 was also included as one of the measurement tools (Ware and Sherbourne 1992) (see Table 2.4).

Jelsness-Jørgensen (2011) conducted a study to describe the impacts of diabetic foot ulcers on patients' health-related quality of life. The researcher also compared the experience of patients with and without complications related to diabetic foot ulcers. The study involved 130 diabetic outpatients and 127 diabetic foot ulcer patients. The patients' health-related quality of life was measured using SF-36 (Ware and Sherbourne 1992) (see Table 2.4).

In Iran, Sanjari et al. (2011) conducted a cross-sectional comparative study on 54 patients with diabetic foot ulcers and 78 patients who had diabetes without foot ulcers. The aim of the study was to describe the impact of diabetic foot ulcers on the patients' health-related quality of life using SF-36 (Ware and Sherbourne 1992) (see Table 2.4).

Morales et al. (2011) investigated the impact of foot ulcers on various aspects of patients' health-related quality of life. The SF-36 (Ware and Sherbourne 1992) was used to assess the health-related quality of life of 258 diabetic patients without foot lesions, and the results were compared with the findings of 163 patients suffering from diabetic foot ulcers (see Table 2.4).

The only study that examined the health-related quality of life of patients with diabetic foot disease in Malaysia was one by Mazlina et al. (2011). The study aimed to evaluate the impact of foot problems on the health-related quality of life of diabetic patients in Malaysia. The SF-36 (Ware and Sherbourne 1992) was used to assess the health-related quality of life of 140 diabetic patients with foot problems and the results were compared with the findings from 134 diabetic patients without foot problems. The patients were those who attended an outpatient diabetic foot clinic in University of Malaya Medical Centre (see Table 2.4).

de Meneses (2011) also used a cross-sectional comparative study to evaluate the health-related quality of life and self-esteem of patients with diabetic foot ulcers. The study was conducted on 15 patients with diabetic foot ulcers and 20 patients without diabetic foot ulcers who attended outpatient clinics in Pouso Alegre, Brazil. Health-related quality of life and self-esteem were assessed using the SF-36 (Ware and Sherbourne 1992) and the Rosenberg Self-Esteem Scale (see Table 2.4).

The other seven quantitative studies were cross–sectional studies that examined the health-related quality of life of patients with diabetic foot ulcers only. Evans and Pinzur (2005) measured the impact of foot ulcers on the physical, mental, emotional, and social aspects of diabetic patients' lives. The study particularly investigated 34 randomly selected diabetes patients with foot ulcers who attended a diabetic foot clinic. The evaluation tools used in this study consisted of SF-36 (Ware and Sherbourne 1992) and the American Academy of Orthopaedic Surgeons (AAOS) musculoskeletal outcomes measure (see Table 2.4).

One of the first reports of the prevalence of pain associated with diabetic foot ulcers was published by Ribu et al. (2006). This study was conducted on 127 patients with diabetic foot ulcers from six hospital-based diabetic outpatient clinics in Norway. The aims of the study were to describe the prevalence and occurrence of diabetic foot ulcer pain as well as its impact on the patients' health-related quality of life. The occurrences of pain at night and while walking/standing were assessed using specific components of the diabetic foot ulcer scale (DFS) (Abetz et al. 2002). Additionally, SF-36 (Ware and

Sherbourne 1992) and DFS, which is a disease-specific measure (Abetz et al. 2002), were used to measure the patients' health-related quality of life (see Table 2.4).

In another study, Bengtsson et al. (2008) carried out a cross-sectional study to investigate whether patients with neuropathic or neuroischaemic ulcers have experienced pain. A total of 101 consecutive patients attending an outpatient foot clinic participated in this study. The measure of pain was assessed using a validated 10 mm visual analogue scale (VAS) (see Table 2.4).

Bradbury and Price (2011a) and Bradbury and Price (2011c [phase 1]) conducted a cross-sectional study in the United Kingdom using the short-form McGill pain questionnaire (SF-MPQ) (Melzack 1987). The query explored the presence and the characteristics of diabetic foot ulcer pain in 28 patients with diabetic foot ulcers at a specialist clinic (see Table 2.4).

A large quantitative cross-sectional study was conducted across ten European countries in the Eurodiale study (Siersma et al. 2013). The study was conducted using the Euro-Qol-5D questionnaire - an instrument used to assess health-related quality of life using five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). The study involved 1,232 patients with a new foot ulcer who presented at one of the 14 centres across the region (see Table 2.4).

A recent study by Obilor and Adejumo (2014) was carried out to assess the impact of diabetic foot ulcers on patients' quality of life. The instruments used for data collection included an adapted 37 item-questionnaire of wound-related pain. The intensity of the diabetic foot ulcer pain was assessed with a VAS of 0-10 cm, and quality of life was assessed using the SF-12 (Ware et al. 1996). This study was conducted on 14 patients with diabetic foot ulcers (see Table 2.4).

A cross-sectional study proved to be a good choice for a research design because the method allows the status of a phenomenon to be described along with the relationships among the phenomenon at a fixed point in time (Babbie 2007). According to Burns and Grove (2011), a comparative descriptive design can be adopted when the intention is to describe variables in two or more groups or when a range of settings are involved in the same study. Therefore,

comparisons between two or more groups can be made in order to examine any differences between these groups, and as a basis, it can be presumed that some variations in clinical practice might result from differences in the health-related quality status. However, the cross-sectional design limits the ability of a study to identify the causal relationships between the studied variables and pain (see Table 2.4).

The study by Boutoille et al. (2008) involved a retrospective case control study in order to get a better comprehension of the influence of amputation on the physical and the social aspects of patients' quality of life. This study compared the quality of life of diabetic amputees (25 patients) with a non-amputee group experiencing diabetic foot ulcers (nine patients). The amputees were divided into two groups: those with transtibial amputation (nine patients) and those with toe or transmetatarsal amputation (19 patients). The evaluation method used in this study was SF-36 (Ware and Sherbourne 1992). This study was retrospective because the selected amputation patients were patients who had undergone surgery between early 2002 and early 2004. In a retrospective study, patients were selected to represent both groups with and without a particular disease and were asked about past exposure (McKenna et al. 2010). The weakness of this study is the possibilities of biasedness such as recall biasedness and interview biasedness (Portney and Watkins 2009). For instance, patients may not be able to provide accurate details of the time prior to the onset of any symptoms that may have affected their health-related quality of life (see Table 2.4).

Four of the reviewed studies explicitly identified this study design as a prospective design. A prospective study involves collecting data at one or more points in the future starting with a presumed cause and then looking forward to the presumed effect, aiming to explore what is likely to happen in the future (McKenna et al. 2010; Polit and Beck 2012). Therefore, the timing of survey points needs to be clearly identified in the study (McKenna et al. 2010). Nabuurs-Franssen et al. (2005) conducted a prospective study on 294 patients with diabetic foot ulcers (ulcer duration at least four weeks) and 153 caregivers. The objective of the research was to determine the effects of a foot ulcer on the health-related quality of life of the diabetic foot ulcer patients and their caregivers. The evaluation method used in this study included the SF-36 (Ware

and Sherbourne 1992), which was administered at three points during the study: the first was the baseline measurement obtained (T0 [study entry]); the second measurement was obtained at week twenty, at which the ulcer may have healed or may still persist (T1 [time point at which ulcer may have healed or may still persist at week twenty]); and the third measurement was obtained twelve weeks after T1 (T2 [twelve weeks after T1]) (see Table 2.4).

One prospective study was conducted in the United Kingdom (Winkley et al. 2009). The aim of the study was to describe the change in the quality of life between the baseline and the 18 months follow up in a cohort of people with their first diabetic foot ulcer. The measurement tool included the SF-36 (Ware and Sherbourne 1992). The SF-36 questionnaire was administered at two points during the study, the first of which was the baseline measurement, and the second measurement was obtained at the 18 months follow up (see Table 2.4).

Another prospective study was conducted by Yunus and Rajbhandari (2011) to investigate the prevalence of neuropathic pain between patients with and without diabetic foot ulcers. The study sought to determine whether the patients experienced pain. The measurement tools included a Leeds assessment of neuropathic symptoms and the signs questionnaire (s-LANSS), which is a well validated tool for the diagnosis of painful neuropathy (Bennett et al. 2005). The study examined 44 patients with diabetic foot ulcers and 25 patients with controlled diabetes who attended a general diabetes clinic and a diabetic foot clinic in Lancashire. Yunus and Rajbhandari (2011) clearly stated that the patients in their study were recruited over a period of ten weeks, although they did not clearly explain the time of the survey points (see Table 2.4).

Huang et al. (2012) conducted a prospective and observational study to investigate the characteristics of diabetic patients with diabetic foot ulcers and their health-related quality of life using the SF-36 (Ware and Sherbourne 1992) questionnaire. The study examined 131 consecutive patients who attended a diabetic clinic in Shanghai. The time of the survey points was also not clearly stated in this study, as in the case of Yunus and Rajbhandari (2011) (see Table 2.4).

Studies by Nabuurs-Franssen et al. (2005) and Winkley et al. (2009) gave a clear identification of the time of measurement, which provided the research with a design structure and strengthened the internal validity.

Bradbury et al. (2011) conducted a case series study to evaluate the efficacy of the Silvercel non-adherent dressing. Twenty-six patients with various types of wounds were included in the study. These patients were those with one leg ulcer (*n*= 11), multiple leg ulcers (*n*= 2), a surgical wound (*n*= 3), a pressure ulcer (*n*= 4), and a diabetic foot ulcer (n= 6). The authors attempted to limit biasedness by stating explicit details about the inclusion and the exclusion criteria of the study participants. They also clearly specified the duration of the recruitment of participants, in which the participants were seen in weekly follow-up sessions for twelve weeks or until it was clinically indicated that no further treatment was needed. Wound pain was assessed using standardised local assessment criteria, which included the frequency of wound-related pain (none, intermittent [between dressing changes], at dressing change, continuous [between dressing changes]) and the severity of wound-related pain (mild, moderate, severe, non-evaluable). Wound assessment was assessed as per local standardised criteria, such as the assessment of bed wound, edge and surrounding skin, exudate levels, and the presence of odour (see Table 2.4).

A case series is a study that follows a group of patients who have a similar diagnosis or who are undergoing the same procedure over a certain period (Kooistra et al. 2009). Michael et al. (2008) argued that a case series is appropriate when the author intends to discover new diseases or any rare manifestations of a disease as well as the detection of unexpected benefits or risks of a treatment. However, the absence of a control group markedly limits any conclusion about causality (Michael et al. 2008). Furthermore, the lack of control in external biasedness and internal validity is a critical limitation of this design (Bradbury et al. 2011).

This study is the only randomised controlled trial to evaluate the effectiveness of a polyhexamethylene biguanide foam dressing compared to a similar non-antimicrobial foam for the treatment of a superficial bacterial burden, wound-associated pain, and reduction in wound size (Sibbald et al. 2011). 45 patients with leg (n = 23) and foot (n = 22) ulcers were recruited from two wound healing

clinics in Toronto, Canada, and they were followed for five weeks. Wound characteristics were documented using a standardized tool (NERDS and STONEES checklist) (Woo and Sibbald 2009). The participants were asked to rate their current levels of wound pain prior to the dressing removal on a 5-point Likert verbal descriptor scale. The verbal descriptor scale ranged from ”none,'' ‘‘mild,'' ‘‘moderate,'' ‘‘severe,'' and ‘‘extreme.'' In addition, the participants were asked to indicate their pain levels five minutes after the randomized foam dressing was applied to the wound. This pain assessment utilized the visual analogue scale (VAS) of 0-100 mm. Portney and Watkins (2009) stated that a randomised control trial was used to evaluate new treatments against current treatment, and the trial is seen as the “gold standard” of research for evaluating interventions. Randomisation of participants, the application of an intervention, and the use of a control group are three crucial elements for a randomised controlled trial study (Jirojwong et al. 2014). Sibbald et al. (2004) reported the random assignment of participants and outlined the use of an intervention and a control group with the application of polyhexamethyl biguanide (PHMB) foam dressing as the applied intervention. (See Table 2.4)

It is important that the authors of published studies clearly identify the measures they undertook to test the reliability and validity of their research design (Burn and Grove 2011). One method to assess the reliability of a questionnaire is to perform a pilot study, yet none of the reviewed studies indicated whether a pilot study was carried out prior to the actual research. Given this point, it was difficult to evaluate the accuracy of the data or the credibility of the results (Polit and Beck 2012; Bowling 2009).

2.10.1.2 Sampling

A variety of sampling techniques were used in the reviewed studies. Most of the studies adopted a consecutive sampling technique to recruit the participants. This method is deemed appropriate because most of the studies chose consecutive sampling to recruit the participants. As mentioned by Polit and Beck (2012), consecutive sampling can be considered the best of all nonprobability sampling techniques because it involves taking every patient who meets the selection criteria over a specified time interval or number of patients. Hence, the method makes the sample a better representation of the

entire population compared to other nonprobability sampling techniques. Regarding Obilor and Adejumo's (2014) study, they employed a purposive sampling technique. However, Portney and Watkins (2009) argued that the results of studies using a purposive sampling need to be interpreted with caution because of the risk of biasedness.

Three studies employed random sampling (Ribu et al. 2007; Willrich et al. 2005; Evans and Pinzur 2005; Sibbald et al. 2011). The purpose of random sampling is to ensure that every patient of the population has an equal chance of being selected and that it is not biased (Portney and Watkins 2009). The strength of random sampling is that the sample should represent the target population and eliminate sampling bias.

In a randomised controlled trial, once a sample has been selected, it is important for the researcher to continue the process of randomisation. The purpose of randomisation is to ensure that there is no bias in the allocation of patients to the control or intervention groups (Jirojwong et al. 2014). The description of random assignment outlined in Sibbald et al.'s (2011) study was clearly stated. The participants were randomly allocated into the control group (non-antimicrobial foam) and the treatment group (polyhexamethylene biguanide antimicrobial foam dressing) using a computer-generated randomisation. Then, block randomisation ensured that comparable numbers of subjects with leg and foot ulcers were placed into either the intervention or the control groups. Treatment assignments were kept in sealed envelopes and were opened only after participants' consent had been obtained. To ensure allocation concealment, all dressings and packages appeared the same, with the exception of a letter X or Y printed on the front of the package as the only identifier for treatment assignments. Finally, all clinical investigators and assessors of the study were blinded to the group assignments and their corresponding letters. Explaining the characteristics of a randomised controlled trial in such detail is commendable because such measures help to overcome the weakness of a randomised controlled trial, such as the way participants were assigned into groups.

Six studies (Meijer et al. 2001; Nabuurs-Franssen et al. 2005; Boutoille et al. 2008; Winkley et al. 2009 ; Bradbury et al. 2011; Siersma et al. 2013) did not

explicitly mention the type of sampling approach adopted. Hence, it was difficult to draw conclusions on whether the results can be applied in clinical practice (Polit and Beck 2012).

Most of the other studies explicitly outlined the inclusion and the exclusion criteria used for the sample except the studies by Willrich et al. (2005), Boutoille et al. (2008), Mazlina et al. (2011), Yunus and Rajbhandari (2011), and Siersma et al. (2013). The authors should have discussed the eligibility criteria of their patients in order to decide how representative the sample is to the population being studied.

Sample size is crucially important in quantitative research because a small sample size might not be representative of the whole population, and thus, influences the generalisability of the results (Jirojwong et al. 2014). The sample sizes of the reviewed studies varied between 19 (Obilor and Adejumo 2014) and 1,232 (Siersma et al. 2013) patients. Recruiting a low sample size of less than 30 participants (e.g. Bradbury and Price 2011a; Bradbury and Price 2011c [phase 1]; Bradbury et al. 2011; Obilor and Adejumo 2014) made it difficult to generalise the results to all diabetic foot ulcer patients, especially in clinical settings. Further research is needed to replicate the study findings into a larger population over a longer period.

Calculation of sample size is one of the first and most important steps to be taken in designing a study. However, none of the reviewed studies apart from the one by Goodridge et al. (2006) reported any sample size calculation, which could also be considered as a weakness in any quantitative research. Goodridge et al. (2006) stated that a power analysis of 80% was used to calculate their sample size.

2.10.1.3 Ethical considerations

Studies that involve human participants require ethical approval prior to them being carried out. The purpose is to ensure that participants' rights, dignity, and privacy are protected and that the potential risks to the participants are minimised (Denzin and Lincoln 2005). Ethical approval can be achieved by ensuring that (1) the national ethics committee approves the study, (2) the respondents give their informed consent, and that (3) their right to confidentiality

and anonymity is maintained (LoBiondo-Wood and Haber 2014). Nine of the studies reviewed (Nabuurs-Fransen et al. 2005; Goodridge et al. 2006; Ribu et al. 2006; Ribu 2007; Winkley 2009; de Meneses et al. 2011; Morales et al. 2011; Sanjari et al. 2011; Sibbald et al. 2011) obtained ethical approval as well as consent from the patients participating in the study. However, in five of the studies, only consent from the patients was obtained (Willrich et al. 2005, Yunus and Rajbhandari 2011, Jelsness-Jørgensen 2011 et al. 2011, Bradbury and Price 2011a and Bradbury and Price 2011c [phase 1]). Bradbury and Price (2011a) and Bradbury and Price (2011c [phase 1]) maintained that an ethical approval from the committee was not required because the results from their study would be used only for audit purposes and were within the realms of normal clinical practice. In two other studies, Mazlina et al. (2011) and Obilor and Adejumo (2011) obtained approval solely from the ethics committee while in other studies, no mention was made of whether the authors obtained any form of approval from either the committee or the patients (Meijer et al. 2001; Evans and Pinzur 2005; Bengtsson et al. 2008; Bradbury et al. 2011; Siersma et al. 2013).

Apart from the study done by Bradbury et al. (2011), all the reviewed studies required the participants to complete a questionnaire. This method is considered not invasive, and therefore, in theory, ethical approval was not required. However, this is an incorrect perception because some questions may require participants to recall sensitive memories, which may invade their privacy (Parahoo 2006). In Bradbury et al.'s (2011) study, the patients were tested for the efficacy of Silvercel non-adherent dressing on their wound. This process placed the participants at risk and extra precautions were needed to protect them.

2.10.2 Qualitative studies

2.10.2.1 Research design

A qualitative research is an act to study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them. It is intended to penetrate to the deeper

significance that the subject of the research ascribes to the topic being researched (Denzin and Lincoln 2000). A qualitative approach allows personal experience and thoughts to be expressed (Creswell 2007). The methodology was appropriate for all four studies as the authors were looking to investigate the patients' experiences (see Table 2.5).

Two of the reviewed studies (Ashford et al. 2000; Watson-Miller 2006) adopted the phenomenology method to explore the experiences of quality of life of diabetic foot ulcer patients. Three of the studies (Ribu and Wahl 2004; Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]) used an exploratory qualitative method to explore the effects of diabetic foot ulcer pain on patients' quality of life (see Table 2.5).

Ashford et al. (2000) adopted a phenomenological approach using semi-structured conversational interviews with 21 diabetic foot ulcer patients from an outpatient diabetic foot ulcer clinic. They conducted the study to address the quality of life issues among patients with diabetic foot ulcers. In a similar study, Watson-Miller (2006) also adopted a phenomenological approach to understand the experience of six diabetic foot ulcer patients in Bermuda. Using a hermeneutic phenomenological study, the data were collected through unstructured interviews via audiotape. The phenomenology approach was considered appropriate for the study because the researcher had sought to understand the phenomenon of a person living with diabetic foot ulcers (Creswell 2007) (see Table 2.5).

Three of the studies explicitly identified the study design as an exploratory qualitative method. Ribu and Wahl (2004) conducted a qualitative study to discover patients' perspective of living with diabetic foot ulcers. Seven patients with diabetes and leg or foot ulcers were identified by district nurses to participate in the study. A series of in-depth recorded interviews were performed using interview guides developed from previous studies. Bradbury and Price (2011b) and Bradbury and Price (2011c [phase 2]) conducted a qualitative study to investigate the impact of diabetic foot ulcer pain on patients' health-related quality of life. The study involved three patients with diabetic foot ulcers in a specialist outpatient diabetic foot clinic. After identifying the patients who were suffering from diabetic foot ulcers/ diabetic foot ulcer pain, face-to-face

semi-structured interviews were performed in this study. The aim of the study was to explore the impact of the diseases on the patients' quality of life. The method was considered appropriate because a qualitative study involves studying people in their natural settings and the exploration of individuals' with diabetic foot ulcers/ diabetic foot ulcer pain to obtain rich and insightful data (Bowling 2002) (see Table 2.5).

2.10.2.2 Sampling

Three of the studies adopted purposive sampling (Watson-Miller 2006; Bradbury and Price, 2011b; Bradbury and Price, 2011c [phase 2]). Purposive sampling refers to the selection of participants with particular characteristics that will best help the researcher to understand the problems and the research questions (Bowling 2002; Creswell 2007). The method is often used in qualitative studies that aim to gain insight and understanding rather than to assume representativeness and generalise results (Patton 2002). The other two studies do not state the sampling method adopted (Ashford et al. 2000; Ribu and Wahl 2004).

With regard to the eligibility criteria, two studies (Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]) explicitly outlined the inclusion and exclusion criteria used for the sample except for the studies by Ashford et al. (2000), Ribu and Wahl (2004), and Watson-Miller (2006). The inclusion and exclusion outlines provide details of the representativeness of the sample to the studied population.

The sample size was between three (Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]) and 21 patients (Ashford et al. 2000). This size is considered relevant to a qualitative study because qualitative research does not aim at generalising from the sample but rather at developing an in-depth understanding from a small number of participants (Creswell and Plano Clark 2011).

2.10.2.3 Reflexivity

Reflexivity is the process in qualitative research whereby the researcher reflects continuously on how his or her own actions, values, and perceptions affect the research setting and could affect the data collection and interpretation (Gerrish and Lacey 2010). In three of the studies (Ashford et al. 2002; Ribu and Wahl 2004; Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]) no information or recognition were given in relation to the researchers' position in the studies. Watson-Miller (2006) mentioned that her own thoughts were not eliminated or bracketed and her pre-understandings and prejudices were also brought into the research process. It was clear that the author tried to avoid any bias that might occur by accidentally reporting her interpretation of patients' feelings.

2.10.2.4 Ethical consideration

Three of the studies (Ribu and Wahl 2004; Watson-Miller 2007; Bradbury and Price 2011c; Bradbury and Price (2011b [phase 2]) included a section on ethical considerations, which is crucial in nursing research. It was evident that to conduct the studies, ethical approval was required from the appropriate bodies. The authors also stated that they gained informed consent from the patients prior to commencing the study. Nevertheless, Ashord et al. (2000) made no mention of ethical approval or informed consent of their research.

Reports regarding consideration by an ethics committee and whether informed consent was obtained from patients should always be included as some questions may ask participants to recall sensitive memories and this may invade their privacy (Parahoo 2006). Ethical approval is crucial in order to protect participants and is therefore an important element of research.

2.11 Synthesis of study findings

Despite the methodological limitations of the previous studies, some collective trends were identified from the literature review. The issues include:

- Diabetic foot ulcer pain assessment
- Pain in diabetic foot ulcers

- Diabetic foot ulcers, pain, and health-related quality of life
- Wound care and diabetic foot ulcer pain

Discussion on the above issues and critical analysis of the reviewed studies are presented in the following subsections.

2.11.1 Diabetic foot ulcer pain assessment

In the reviewed studies, three validated pain rating scales were used by the diabetic foot ulcer patients to assess their pain status. The SF-MPQ (Melzack 1987) was used in two of the studies (Bradbury and Price 2011a; Bradbury and Price 2011c [phase 1]), while the s-LANSS was used in one study (Yunus and Rajbhandari 2011). The VAS was used in three studies (Bengstsson et al. 2008; Obilor and Adejumo 2014; Sibbald et al. 2013). However, in Ribu et al.'s (2006) study, pain was assessed by using two items from the physical health domain of the diabetic foot ulcer scale (DFS) (Abetz et al. 2002) and by asking the patients whether they had experienced any pain while walking or standing. In the study by Bradbury et al. (2011), pain was assessed using the following standardised local assessment criteria: the frequency of wound-related pain (none, intermittent (between dressing changes), at dressing change, continuous (between dressing changes) and the severity of wound-related pain (mild, moderate, severe, non-evaluable). In the other studies, pain was assessed using a five-point Likert scale (''none,'' ''mild,'' ''moderate,'' ''severe,'' and ''extreme'') (Sibbald et al. 2013), the domain of the AAOS musculoskeletal outcomes measure (Evans and Pinzur 2005), and the domain of the SF-36.

The SF-MPQ was developed by Melzack (1987) to measure the different qualities of subjective pain experience. The questionnaire contains eleven sensory words and four affective words. The SF-MPQ also includes one item to present pain intensity and one item for a 100-mm VAS for average pain. It was validated in patients with different types of pain, and it has an adequate internal reliability. The questionnaire was also translated into English, French, Chinese, Czech, Danish, Farsi, Greek, Hebrew, Hindi, Korean, Norwegian, Swedish, Thai, Turkish, and Malay (Hawker et al. 2011).

The s-LANSS was developed by Bennet et al. (2005) to measure the symptoms and signs in neuropathic pain. The tool contains seven items and was validated in patients with different types of pain. It also has adequate internal reliability (Bennett et al. 2005; Hallström and Norrbrink 2011; Elzahaf et al. 2013). However, its validity and reliability has been established in English, Swedish, and Arabic, but not in Malay.

The VAS is a unidimensional measure of pain intensity that has been widely used in diverse adult populations (Hawker et al. 2011). It is one horizontal or vertical line 10 cm (100 mm) in length. The respondent is told to anchor “no pain” as a 0 and “worst pain possible” as 10 (Burckhardt and Jones 2003).

In conclusion, only four validated measurements for pain were used in diabetic foot ulcer studies, such as the SF-MPQ, the s-LANSS, and the VAS. In Sibbald et al.’s (2013) study, however, they adopted a five-point Likert scale while Bradbury et al. (2011) used the standardised local assessment criteria for the measurement of pain. These measurements may be questionable because in neither study did the authors discuss the validity and reliability of the measurement. In other studies, a formal pain assessment was not used and instead, the researchers adopted domains from the DFS, the domain of the AAOS musculoskeletal outcomes measure, and the domain of SF-36. This is because the primary aim of the study was not to evaluate the specifics of diabetic foot ulcer pain. Therefore, the SF-MPQ was found to be the most appropriate because the tool was designed to measure the sensory and affective aspects of pain and pain intensity (Hawker et al. 2011).

2.11.2 Pain in diabetic foot ulcer

Studies have shown that wound-related pain has a significant impact on patients’ quality of life (Price et al. 2008). Wound-related pain affects the physical, psychological, and social well-being of the patients. Because pain limits physical activities, and social contact, it can contribute to anxiety and depression (Wounds International 2012).

There has also been a misconception that pain or discomfort does not occur in either neuropathic or neuro-ischaemic foot ulceration. This is not entirely true for

all patients, who despite having peripheral neuropathy, may report severe and frequent pain (Bradbury and Price 2011a; Bradbury and Price 2011c).

Diabetic foot ulcer pain was examined in six of the studies. A Norway diabetic foot ulcer pain prevalence study testified that 75% of patients had reported "some pain" in relation to diabetic foot ulcers (Ribu et al. 2006). Furthermore, 57% of the patients also reported ulcer pain while walking and/or standing and at night. This study also revealed that socio-demographic and clinical and ulcer characteristics were not significantly associated with any pain group. However, these findings are questionable because the sample was split into three groups: those who experienced pain none of the time, a little or some of the time, and most or all of the time. These groups were relatively small in size, which might affect the authors' ability to draw definitive conclusions about the differences in clinical characteristics among the three groups of patients. In relation to health-related quality of life, both the SF-36 and the DFS revealed significant differences between the three groups. Patients with the lowest scores in the physical and psychological domains of the questionnaire proved to have experienced pain either all the time or most of the time.

Similar findings were reported by Bengtsson et al. (2008), who investigated whether patients with neuropathic or neuroischaemic ulcers have experienced pain. The study revealed that 53% of the 101 patients reported having wound-related pain either intermittently or continuously. It was also reported that the presence of pain did not vary between aetiologies, with 34% of the patients with neuropathic ulcers reporting continuous pain compared to 30% of the neuro-ischaemic patients. The findings also concluded that the patients had encountered ulcer pain while walking, during dressing changes, and at night. The patients also described different feelings of pain, such as stinging, pricking, sore, burning, and pulsating/gripping.

A similar effect on pain was found in people with diabetic foot ulcers. Yunus and Rajbhandari (2011) surveyed the prevalence of neuropathic pain by ascertaining whether patients with and without diabetic foot ulcers had experienced the pain. In this study, 43.2% of the patients with diabetic foot ulcers had signs and symptoms of painful neuropathy, while only 18.2% had sought treatment. The authors noticed that the patients were often more

concerned about their visible ulcer than about the invisible pain, and they appeared to ignore the symptoms of neuropathic pain (Yunus and Rajbhandari, 2011). The results showed that 43.2% of the participants with diabetic foot ulcers had symptoms and signs of painful neuropathy. The s-LANSS score was significantly higher in the diabetic foot ulcer group (8.1± 7.7 versus 4.7 ±4.6; *P*= 0.04) than in those without foot ulcers. However, there was no difference in the perception of pain in the 10-point Likert scale (3.9± 3.6 versus 3.3 ± 3.0; *P*= not significant) between these two groups, which means that the patients with diabetic foot ulcers may have suffered from neuropathic pain but did not report it.

Another study describing the effects of pain found in people with diabetic foot ulcers was carried out by Bradbury and Price (2011a) and Bradbury and Price (2011c [phase 1]). Using the SF-MPQ (Melzack 1987), Bradbury and Price explored the presence and the characteristic of diabetic foot ulcer pain in 28 patients with diabetic foot ulcers at a specialist clinic. The study found that 86% (n=24) of the patients had reported diabetic foot ulcer pain with a mean VAS score of 26.36 (SD=24.29). Patients with neuro-ischaemic ulceration (*n*=13) reported a higher mean score (mean= 32.2, SD= 24.6) compared to patients with neuropathic ulceration (mean= 21.6, SD= 24.6). Using the SF-MPQ, the authors found the patients were more likely to use five descriptors: aching, hot-burning, tender, sharp, and tiring/exhausting. These painful sensations indicate a combination of nociceptive (aching, tender) and neuropathic (hot-burning, sharp) pain.

In a recent study by Obilor and Adejumo (2014), pain was examined in 14 patients with diabetic foot ulcers. Their finding showed that all the participants experienced diabetic foot ulcer-related pain either at rest (*n*= 4), during the performance of ADL particularly in their movement (*n*= 8), or at night (*n*= 5). Measuring pain intensity on a VAS of 0–10 cm, the majority of the patients (85.7%, n= 12) reported the experience to be of moderate to severe pain intensity, with a mean of 5.43 (SD 2.24, range 2–10). The patients frequently chose words such as stinging, tingling, sharp, stabbing, throbbing, and aching. These painful sensations indicate a combination of nociceptive (sharp, stabbing, throbbing, aching) and neuropathic (stinging, tingling) pain. In terms of health-related quality of life, the diabetic foot ulcer-related pain experienced by

the patients was found to be significantly related to the physical functioning, social functioning, and general mental health domains of the SF-12, with a majority of the patients having lower scores in both physical and psychological domains.

In conclusion, only six studies were found to have focused specifically on individuals with diabetic foot ulcer pain. Nevertheless, all the studies highlighted the need for further research to examine diabetic foot ulcer pain.

2.11.3 Diabetic foot ulcers, pain, and health-related quality of life

A large and growing body of literature has documented the health-related quality of life of patients with diabetic foot ulcers (Meijer et al. 2001; Willrich et al. 2005; Evans and Pinzur 2005; Nabuurs-Franssen et al. 2005; Goodridge et al. 2006; Ribu et al. 2007; Boutoille et al. 2008; Winkley et al. 2009; Jelsness-Jorgensen et al. 2011; de Meneses et al. 2011; Morales et al. 2011; Sanjari et al. 2011; Mazlina et al. 2011; Huang et al. 2012), but studies that focus on the pain experience of people with diabetic foot ulcers are limited in number. In the reviewed studies, pain is often discussed in terms of the relationship between diabetic foot ulcers and health-related quality of life. One example is the study by Nabuurs-Franssen et al. (2005), who from the SF-36 indicated that those patients with persisting ulcers had lower health-related quality of life scores than those with healed ulcers, particularly in physical functioning. The findings of the study also revealed that compared to persistent ulcer patients, patients with healed ulcers had complained of pain. As for the caregivers, the study reported that they had felt a large emotional burden due to having to take care of patients with diabetic foot ulcers.

The above findings supported the discovery by Ribu et al. (2007) in relation to the effects of quality of life of people with diabetic foot ulcers. The results showed that the diabetic foot ulcer group had significantly lower scores in all the SF-36 subscales compared to both the diabetic and nondiabetic general population, particularly in areas concerned with physical health and performing ADL. The authors also acknowledged that compared to diabetic patients, patients with diabetic foot ulcers had complained about having more pain, but

did not explain the cause of their pain. The authors then recommended future research on diabetic foot ulcer-related pain.

Similar to previous studies conducted in the European countries, patients with diabetic foot ulcers in Asia are also affected in terms of physical functioning and mental health. A study by Huang et al. (2012) on 131 consecutive patients who attended a diabetic clinic in Shanghai revealed that the scores in the subscale of physical functioning were low in diabetic foot ulcer patients. The study also statistically attested the significance of bodily pain among patients with diabetic foot ulcers. In another study, Boutoille et al. (2008) confirmed that having a diabetic food ulcer has a great influence on patients' quality of life especially in the bodily pain domain. Nonetheless, the discussion was limited to the relation of foot ulcers to peripheral arterial disease.

A similar condition was observed in Malaysia. One example is a local study conducted by Mazlina et al. (2011) on 140 diabetic patients with foot problems and 134 diabetic patients without foot problems at an outpatient diabetic foot clinic in University Malays Medical Centre, Malaysia. The result from all the eight SF-36 domains indicated that patients with foot problems had lower health-related quality of life scores than those without foot problems, In particular, restrictions in physical functioning limited the patients' abilities to perform daily living activities, and they also had bodily pain. This study supported the necessity for further exploration of the issue of pain and diabetic foot ulcers.

A large quantitative cross-sectional study was conducted by Siersma et al. (2013) across ten European countries participating in the Eurodiale study. In the study, the patients reported a poor overall health-related quality of life, with problems primarily in the mobility and pain/discomfort domains. Among the comorbidities, the inability to stand or walk without help was the most important determinant of a decreased health-related quality of life in all five domains of the Euro-Qol-5D. The authors suggested that a clinical diagnosis of infection, peripheral arterial disease, and polyneuropathy were associated with the pain/discomfort domain.

Other studies have attested that pain is not a significant factor among diabetic foot ulcer patients (de Meneses et al. 2011; Goodridge et al. 2006; Meijer et al.

2001; Evans and Pinzur 2005; Willrich et al. 2005). For example, in a study by Meijer et al. (2001), the results from the RAND-36 and the WWSQ indicated lower scores for patients with diabetic foot ulcers than for those without diabetic foot ulcer. The researchers also concluded that even a clinically stable diabetic foot ulcer may cause significant impairment in the quality of life, particularly in the domains of physical functioning, social functioning, physical role, and health experience. However, there was no mention of the relationship between having a diabetic foot ulcer and pain. This contradicts the findings of other studies, which suggested pain was a significant factor. In addition, no significant difference was noted in the daily living activity of the patients (Meijer et al. 2001). This study did not support the hypothesis that pain from diabetic foot ulcers is prevalent and has a significant influence on a patient's quality of life.

In Goodridge et al.'s (2006) cross-sectional study, they conducted a descriptive study to compare the quality of life between patients with active and patients with healed foot ulcers. The findings showed the unhealed diabetic foot ulcer group reported significant limitations on their activities, work, and social life, even if the diabetic foot ulcer had a low Wagner classification grade. There was little difference between the two groups with regard to the effect of pain on their activity; 40% of the participants in each group did not consider pain to be a problem. In addition, no difference was noted in the mental health domain between the two groups. Similar to the study by Meijer et al. (2001), this study also did not support the hypothesis that pain from diabetic foot ulcers is prevalent and has a significant influence on patients' quality of life. However, the study adds to the body of knowledge on this area while supporting other findings on the negative impacts of diabetic foot ulcers on quality of life.

In a quantitative study, Evans and Pinzur (2005) measured the impacts of foot ulcers on the physical, mental, emotional, and social aspects of patients' lives. The results revealed a statistically significant difference in the physical functioning of the patients. Although pain was not a significant component in this study, the diabetic foot ulcer patients complained of extreme pain during resting, walking on an uneven surface, and stair climbing. The results of the study will be a platform for further investigation on diabetic foot ulcer pain and health-related quality of life.

In qualitative studies, pain is a dominant theme and is consistent across all studies (Ribu and Wahl 2004; Ashford et al. 2000; Watson-Miller 2006; Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]). In these studies, pain was significant; it was described as the worst symptom and had a profound effect on the quality of life of the patients. Ribu and Wahl (2004) conducted a qualitative study to understand the patients' perspective of living with diabetic foot ulcers. The data analysis revealed six categories of problems commonly experienced in relation to living with diabetic foot ulcers, one of which concerned pain. The study found that almost all the patients experienced pain at some time. Although one patient discussed it in relation to an active Charcot arthropathy, others reported how pain from the ulcer had woken them up at night and how they had to recline in certain positions to avoid any pressure on the ulcer, which would cause pain. The patients also claimed that pain was felt while walking even for short distances. The study also highlighted the effects of pain in causing sleep deprivation and fatigue, which affected the overall quality of life. In the study, three patients avoided taking analgesia despite experiencing pain due to a fear of analgesia dependency.

In a similar study using a phenomenological approach, Ashford et al. (2000) conducted research to address the quality of life issues among patients with diabetic foot ulcers. The results suggested that the patients suffered emotionally, financially, physically, and socially due to diabetic foot ulcers. The data analysis also revealed six categories of problems commonly experienced in relation to living with diabetic foot ulcers, one of which concerned pain. Half of the patients (50%) reported pain arising from the ulcer. Pain was also reported during dressing change and while lying down. The ulcer pain had also caused the patients difficulty in walking and resulted in reduced mobility. The study was successful in its aims to allow the diabetic foot ulcer patients to express their thoughts on issues regarding their quality of life and diabetes. Accordingly, the authors suggested that it is crucial for healthcare providers to use a holistic approach when dealing with patients with diabetes.

Watson-Miller (2006) investigated the experiences of six patients of living with diabetic foot ulcers. The participants shared their experiences and reported that the pain caused by diabetic foot ulcers had had negative effects on their quality of life. Although Watson-Miller (2006) did not investigate this aspect further, the

author highlighted the importance of making a holistic assessment of people's quality of life. The author also emphasised the need for clinicians to be aware of the difficulties of people with diabetic foot ulceration. Interestingly, the patients in this study did not report any social isolation. However, it should be noted that this study had a very small number of participants and that the results are not comparable to the findings reported in other studies, which did note the problem of social isolation (Ribu and Wahl, 2004; Bradbury and Price 2011b). Bermuda is a very small country, and the people tend to be very sociable with many opportunities to support one another.

The most recent qualitative study on the health-related quality of life of patients with diabetic foot ulcers was undertaken using face-to-face semi-structured interviews with three diabetic foot ulcer patients from a specialist outpatient diabetic foot clinic (Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]). Four major themes emerged linking pain and quality of life: the experience of pain; the physical effects of pain; coping, support and social impact and the psychological impact. The study found that as a result of diabetic foot ulcer pain, the patients were affected physically and psychologically particularly with regard to mobility, sleep, and social life. Pain was also reported during dressing changes and while lying down. The ulcer pain also caused the patients difficulty in walking. The study also identified the diabetic foot ulcer patients' feelings of depression, isolation, and loss of independence, which appeared to be the consequences of ulcer pain. The strength of this study is that it identified a significant gap in the research; for those diabetic foot ulcer patients who experienced pain, the pain, in turn, had negative impacts on their quality of life. Further qualitative research was recommended into the patients' lived experiences of diabetic foot ulcer pain in order to help healthcare professionals understand the relevance of holistic diabetic foot care and service provision.

Other studies have revealed little about pain and its impacts, as their purpose was not focused on pain specifically (Willrich et al. 2005; Winkley et al. 2009; Jelsness-Jorgensen et al. 2011; de Meneses et al. 2011; Morales et al. 2011; Sanjari et al. 2011).

The conclusion derived from the study is that the reduced quality of life among diabetic patients can be attributed to the pain experienced by them. Despite a number of studies having looked into the relationship between health-related quality of life and diabetic foot ulcers, none has included a detailed discussion on the effects of pain. This objective appears not to be the primary aim of most of these studies; thus, their findings may not be used to draw substantial conclusions on the subject. However, the discoveries can provide scholars with a background of the subject and pave the way for a detailed study on the nature and degree of pain. Such studies are considered necessary to fill in the gap in the existing body of knowledge.

2.11.4 Wound care and diabetic foot ulcer pain

Wound dressings play a significant role in the management of diabetic foot ulceration (Hilton et al. 2004). The ideal dressings should alleviate symptoms, provide wound protection, and encourage healing (Hilton et al. 2004). In one study, Hollinworth and Collier (2000) investigated nurses' knowledge of wound pain and found that 80% of the nurses (*n*= 225) noticed that patients experienced most pain during dressing change particularly at the time when the dressing was being removed. Research into the dressing-change experiences of patients with diabetic foot ulcers is still very scarce compared to studies on the experiences for other types of wounds. Furthermore, minimal study has been carried out to explore the potential effects of pain on patients with diabetic foot ulcers. Five studies have provided evidence on the experience of pain at the time of dressing change (Ashford et al. 2000; Bengtsson et al. 2008; Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]; Obilor and Adejumo 2014). For example, to validate the experience of pain during dressing change, Obilor and Adejumo (2014) examined the pain associated with wound care of fourteen patients with diabetic foot ulcers. A total of 78.6% (*n*=11) of the patients experienced pain during the dressing change of their foot ulcer. Of this number, 54.5% (*n*=6) rated the pain as moderate in intensity. In the same study, ten patients reported having experienced pain immediately after the dressing change while two patients complained that the diabetic foot ulcer pain started immediately after the dressing change and continued until the next day's dressing. The patients also reported having experienced the highest level of

pain during the removal of old dressings, followed by the removal of the old dressing's bandage/plaster and wound cleansing. As in the study by Bengtsson et al. (2008), they highlighted that nineteen out of the fifty-three patients (36%) stated that the dressing change had aggravated their diabetic foot ulcer pain.

Several factors were found to have contributed to pain during dressing change. In an international survey of 3,918 practitioners, dried-out dressings and wound dressing products that adhere to wounds were identified as two of the most important factors that contribute to trauma and pain during a dressing change (Mofatt et al. 2002). Numerous topical regimens are available for the management of diabetic foot wounds, such as saline-soaked gauze dressings, foams dressings, gel dressings, and antimicrobial dressings. Saline-soaked gauze dressings have been used as a standard treatment for diabetic ulcers. Such dressings are simple and inexpensive (Hilton et al. 2004). Foam-based dressings are another popular choice for diabetic foot ulcer management (Hilton et al. 2004). The foam dressings have a wide range of absorbency, provide moisture control, and offer conformability to the wound bed; they are also easy to cut into shape (Hilton et al. 2004; International Best Practice Guidelines 2013). Examples of foam dressings include the Allevyn (Smith and Nephew) and the Cavicare (Smith and Nephew). Hydrogel dressings are designed to facilitate the autolysis of necrotic tissue. Examples of hydrogels include the Aquaform (Maersk Medical) and the Intrasite Gel (Smith and Nephew) (Hilton et al. 2004). Antimicrobial dressings have been used for the treatment of diabetic foot wounds. They act as an antibacterial agent against several types of infections (Wounds International 2011). Examples of antimicrobial dressings are silver, cadexomer iodine, polyhexamethyl biguanide (PHMB), and honey (Wounds International 2011).

Diabetic foot ulcer pain associated with treatment was reported in two of the studies (Sibbald et al. 2011; Bradbury et al. 2011). Sibbald et al. (2011) randomised 23 leg ulcer patients and 22 diabetic foot ulcer patients who were treated using either PHMB antimicrobial foam dressings or regular foam dressings without an antimicrobial foam dressing. Pain was assessed via a 5-point Likert verbal descriptor scale (''none,'' ''mild,'' ''moderate,'' ''severe,'' and ''extreme'') and the VAS of 0-100 mm. At the baseline, pain assessments were comparable between the two groups (33.3% no pain PHMB foam group versus

31.6% in the control group, P = .79). At week 2, a higher proportion of subjects in the PHMB foam group (78.9%) reported no pain prior to dressing change compared to those in the control group (33.3%), as measured by the 5-point Likert scale. The difference was significant (P = .0006). In week 4, pain ratings remained consistently lower, with 73.7% in the PHMB group reporting no pain (P = .02) versus 38.1% in the control group. Furthermore, at week 2, the pain levels at 5 minutes after the dressing application were also assessed via the VAS. The same trend in pain reduction was apparent, with subjects in the PHMB foam group reporting greater comfort compared to the control group (P = .05). After five weeks, patients who were treated with PHMB foam dressing reported that pain was reduced compared to those in the control group. Therefore, the authors concluded that the PHMB antimicrobial foam dressing was more effective in reducing chronic wound pain and bacterial burden.

Bradbury et al. (2011) evaluated the impact of using Silvercel non-adherent dressings on twenty-six patients with various wound types. Wound pain was assessed using standardised local assessment criteria, which include the frequency of wound related pain (none, intermittent [between dressing changes]), during dressing change, continuous (between dressing changes) and severity of wound-related pain (mild, moderate, severe, non-evaluable). Out of the twenty-six patients, three reported a relatively more intense pain, which led to the discontinuation of the dressing; one patient complained of having discomfort during application; one patient reported that the pain increased with this type of dressing; and the last patient complained of a burning sensation when the dressing was applied. In contrast, nine patients claimed that their pain was reduced during the application of the dressing. Another six patients reported a decrease in pain or no pain at all. The authors concluded that the silvercel non-adherent dressing was effective in minimising wound pain.

2.11.5 Summary of literature review and justification of current study

In summary, the literature review established that diabetic foot ulcer pain significantly affects the physical, social, and the psychological aspects of health-related quality of life. Pain was identified as a major concern, with reports often ignored.

The major drawback of this review is that no study specifically focused on respondents aged 60 and above. Though the studies had varying representations of this group, they were mostly carried out with a small sample size. This means that no conclusions about pain, health-related quality of life, and functional status can be drawn for the age group of people aged 60 years above. Thus, this can be considered an important area for further research.

Another issue identified from the literature review was the different scales or instruments used in the studies. These scales probably measured different facets of the phenomena and therefore cannot be interpreted interchangeably. For example, although Ribu et al. (2006) actually acknowledged that diabetic foot ulcer pain was important, they did not perform any formal assessments on the patients because the study primarily aimed to evaluate the specifics of diabetic foot ulcer pain. Most of the studies used generic health-related quality of life questionnaires to measure patients' quality of life. Goodridge et al. (2006) pointed out that the generic quality of life questionnaires, such as the SF-36, are not sensitive enough to indicate the presence of an ulcer or a change in ulcer status. In fact, only one study adopted the Barthel Index Score questionnaire (Mahoney and Barthel 1965) to assess functional status in this review. This raised the need of ascertaining which questionnaires can best measure pain and its relationships with health-related quality of life and functional status.

In terms of research methods, the most common limitations of the quantitative studies were the small sample size, the lack of reporting of a sample size calculation, and the inexplicit inclusion and exclusion criteria. For instance, in the study by Bradbury and Price (2011a) and Bradbury and Price (2011c [phase 1]), limited inferential statistic was applied due to the small sample size. Similarly, in the study by Bengtsson et al. (2008), no inferential statistic was applied to provide a more detailed information on the relationship between pain sensation and other variables, such as patient demographic data and wound characteristics.

The review indicates that a large number of studies pertaining to this issue have been carried out in the United States and the European countries. However, very little research has been conducted in Asia, with only one study relating to

health-related quality of life and diabetic foot ulcers being conducted in Malaysia. The study by Mazlina et al. (2010), however, did not evaluate the degree of pain associated with diabetic foot ulcers. Their findings nevertheless suggested that the experience of pain from diabetic foot ulcers has a negative impact on the physical as well as the mental health of patients, and thus, further exploration is required in this area. Despite the increasing number of people diagnosed with diabetes in Malaysia, people are now living longer generally as a result of improvements in nutrition and public health, and advances in medicine. As Malaysia's population is ageing and the prevalence of diabetes is increasing, it is expected that the number of diabetic foot ulcer patients will also increase substantially.

2.12 Summary

This chapter presents the critical review of 27 published studies that explored diabetic foot ulcer pain in detail as well as its relationships between patients' health-related quality of life and functional status. The findings suggest a trend for poorer health-related quality of life of diabetic foot ulcer patients. Overall, it is clear that pain is an important contributor to a reduced health-related quality of life. Unfortunately, these studies did not discuss in detail the effects of pain on these patients, as this was not a primary aim in their investigations.

This chapter also highlights the deficits in the methods adopted in investigating the health-related quality of life of patients with diabetic foot ulcers. Some weaknesses were discovered in the sampling methods, particularly in terms of their leading to potential biasedness. Many of the reviewed studies were of a small scale and had a single focus. Their findings were not sufficiently generalisable to diabetic foot ulcer groups.

A few of the studies adopted inappropriate instruments to measure pain whereby a detailed pain assessment (description and intensity) was not performed. This was because the scope of the studies did not allow for any exploration of the cause of the pain or the study of physical functioning, although most of the studies indicated that patients with diabetic foot ulcers have a poor physical functioning domain. No further discussion was raised because physical functioning was not the primary aim of the investigations.

Several methodological issues posed limitations to the conclusions derived from this critical review. Substantial conclusions cannot be drawn from their results in relation to pain. However, from the critical review of studies to date, it can be deduced that diabetic foot ulcer pain has negative impacts on health-related quality of life and functions in the general population. It is important to note that this is a tentative conclusion due to the lack of rigor in the methodology adopted by some of these studies.

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Meijer et al. 2001 HOLLAND	To compare quality of life between diabetic patients with (former or present) and without foot ulcers.	Cross-sectional comparative study. 14 patients with former or present diabetic foot ulcer. 24 diabetes mellitus patients without foot problem.	RAND-36. Barthel Index Score. Walking and walking stair questionnaire.	Presence of history of diabetic foot ulcers caused a large impact on physical role, physical functioning and mobility. No relation between diabetic foot ulcers and pain and psychological aspect.	Small sample size. No details provided on sample size calculation. No discussion about sampling method. No discussion about ethical approval. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); RAND-36: Research and Development 36-item form (Hays et al. 1993); Barthel Index Score (Mahoney and Barthel 1965).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Willrich et al. 2005 UNITED STATES	To assess health-related quality of life and depression in diabetes mellitus patients with diabetic foot ulcers, osteomyelitis, Charcot arthropathy and LEA.	Cross-sectional comparative study. Two study focus group: 20 patients with diabetic foot ulcers or Charcot foot arthropathy. 20 patients with lower extremity amputation. One control group: 20 patients without foot problems but with peripheral neuropathy.	SF-36. Mini Mental Exam and clock drawing test. Zung self-rating depression scale.	The study showed that the diabetic foot ulcer or Charcot foot arthropathy group had a decrease in perceived functional status and health limitations. There was no relation between having a diabetic foot ulcers and pain No evidence of cognitive impairment or depression in focus group.	No discussion about sampling method. Small sample size. No details provided on sample size calculation. No discussion about ethical approval from ethical committee. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Evans and Pinzur 2005 UNITED STATES	To perform a feasibility trial using American Academy of Orthopaedic Surgeons (AAOS) to assess health-related quality of life in diabetic foot ulcer patients.	Cross-sectional study. Random sampling. 34 patients with diabetic foot ulcer.	SF-36. AAOS. The Global Foot and Ankle Scale.	Patients with diabetic foot ulcers had statistically significant different in the physical functioning. Although pain was not a significant component in this study but diabetic foot ulcer patients were complaint extreme pain during resting, uneven surface and stair climbing. Patients with diabetic foot ulcers reported a negative impact on quality of life in affected individual.	Small sample size. No details provided on sample size calculation. No discussion about ethical approval. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992); AAOS: American Academy of Orthopaedic Surgeons Musculoskeletal Outcomes Measure.

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Nabuurs-Franssen et al. 2005 UNITE KINGDOM, UNITED STATES AND EUROPE	To determine the impact of healing of a foot ulcer on health-related quality of life of diabetic patients and their caregivers.	Prospective study. 294 patients with diabetic foot ulcers (ulcer duration at least four weeks) 153 caregivers.	SF-36. Administered at three points; T0 (study entry) T1 (time point at which ulcer was healed or still persisted at twenty weeks) T2 (twelve weeks after T1).	Patients with persisting diabetic foot ulcers had a lower health-related quality of life than patients with healed diabetic foot ulcer. Healing of foot ulcer resulted in a marked improved of several SF36 subscales 3 months after. Domains included physical functioning, social functioning, role physical, and role emotions. Health-related quality of life decreased progressively when the ulcer did not heal. Patients caregivers had a large emotional burden due to diabetic foot ulcer.	No details provided on sample size calculation. No discussion about sampling method. Not discuss about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Ribu et al. 2006 NORWAY	To describe the prevalence and occurrence of diabetic foot ulcer pain while walking and standing and during the night To describe the impact of diabetic foot ulcer pain on patients' health-related quality of life, using generic and disease-specific instruments.	Cross-sectional study. Consecutive sampling. 127 patients with diabetic foot ulcers.	SF-36. DFS.	75% reported some pain related to diabetic foot ulcers. 57% reported diabetic foot ulcer pain while walking and/or standing and also during the night. 25% reported pain none of the time. The worst health-related quality of life scores were found in patients who reported that diabetic foot ulcer pain occurred "most or all of the time" (either with activity or at night).	A detailed pain assessment (e.g. description, intensity) was not performed. No details provided on sample size calculation. The patients were recruited from specialty clinics. Thus, the findings may not be generalizable to other treatment settings. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992); DFS: Diabetic foot ulcers Scale (Abetz et al. 2002).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Goodridge et al. 2006 UNITED KINGDOM	To compare the quality of life of patients with active and healed foot ulcers.	Cross-sectional comparative study. Consecutive sampling 57 patients with unhealed diabetic foot ulcer. 47 patients with healed diabetic foot ulcers.	SF-12. CWIS.	The results from the SF-12 indicated that the patients with unhealed ulcers had lower quality of life scores than those with healed ulcers, particularly in physical health and issues of limitation to activity and ability to work. There was little difference between the two groups with regard to the effect of pain on activity, and 40% of each group did not consider pain to be a problem.	Small sample size. CWIS was administered to patient with unhealed ulcer alone. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-12: The Medical Outcomes Survey Short Form 12 (Ware et al. 1996); CWIS: Cardiff Wound Impact Schedule (CWIS) (Price and Harding 2004).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Bengtsson et al. 2008 UNITED KINGDOM	To investigate whether patients with neuropathic or neuroischaemic ulcers experience painful sensations in their ulcer and/or lower limbs.	Cross-sectional study. Consecutive sampling. 101 patients with diabetic foot ulcers.	VAS 10 mm.	53 patients experienced painful sensations in the ulcer 32 (60%) continuous pain 21 (40%) intermittent pain. Patients with continuous pain reported a mean VAS score of 5.5 (range 3-10).	No details provided on sample size calculation. The authors did not report at all about gaining approval from either the ethical committee or the patients. This study used descriptive analysis alone. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); VAS: Visual Analogue Score.

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Ribu et al. 2007 NORWAY	To describe health-related quality of life in those with diabetic foot ulcers compared with controls	Cross-sectional comparative study. Random sampling and consecutive sampling. 127 patients with diabetic foot ulcers 221 patients with diabetes. 5903 non-diabetes patients.	SF-36.	The study found that physical functioning and bodily pain. was significantly higher in the foot ulcer-group when compared with diabetes and non-diabetes group.	No details provided on sample size calculation. The effect of comorbidity, which will affect SF-36 scores, was not assessed. Weakness of questions to assess the presence or absence of foot ulcers in the diabetes population. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Boutoille et al. 2008 FRANCE	To evaluate the influence of amputation for diabetic foot ulcers on health-related quality of life.	Retrospective study. 25 patients with amputation. Nine patients with diabetic foot ulcers.	SF-36.	The study found that bodily pain was significantly higher in the foot ulcer-group when compared with the amputation group. There was no significant relationship in physical functioning between these three groups.	No discussion about sampling method. Small sample size. No details provided on sample size calculation. The authors did not report at all about gaining approval either from ethical committee or from the patients. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992)

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Winkley et at 2009 UNITED KINGDOM	To describe temporal changes in health-related quality of life in patients with diabetic foot ulcers over 18 months and the association with adverse outcomes.	Prospective study. 253 patients with diabetes and their first foot ulcer.	SF-36.	Quality of life deteriorates in patient with diabetic foot ulcers whose first ulcer recurs or does not heal within 18 months. There was a significant difference in physical functioning domain but not in bodily pain.	No discussion about sampling method. No details provided on sample size calculation. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Yunus and Rajbhandari 2011 UNITED KINGDOM	To determine the prevalence of painful diabetic peripheral neuropathy in patients with diabetic foot ulcers. To compare between subjects with diabetic foot ulcers and diabetic control.	Prospective study. Consecutive sampling. 36 patients with diabetic foot ulcers. 24 patient as diabetic control were recruited over a period of 10 weeks.	s-LANNS.	43.2% of subjects with diabetic foot ulcers had symptoms and signs of painful neuropathy. s-LANSS score was significantly higher in diabetic foot ulcer group (8.1± 7.7 versus 4.7 ±4.6; *P*= 0.04). There was no difference in the perception of pain in 10- point Likert scale (3.9± 3.6 versus 3.3 ± 3.0; *P*= not significant).	Timing of survey points not clearly stated. No details provided on sample size calculation Inclusion/exclusion criteria not specified. No discussion about ethical approval from ethical committee. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); s-LANSS: Leeds assessment of neuropathic symptoms and signs questionnaire (Bennet et al. 2005).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Jelsness-Jørgensen et al. 2011 NORWAY	To describe health-related quality of life in diabetes outpatient and impact on socio-demographic and/or clinical variables. To compare health-related quality of life in diabetes outpatients with and without diabetic foot ulcers.	Cross-sectional comparative study. Consecutive sampling. 130 Diabetes outpatient group. 127 patients with diabetic foot ulcers.	SF-36.	This study found that diabetic foot ulcers had a major negative impact on 7 of 8 subscales on the SF-36 even after controlling for covariates. The subscales were physical functioning, role physical, bodily pain, general health, vitality, social functioning, and mental health.	No details provided on sample size calculation. No discussion about ethical approval from ethical committee. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims and methodology	Research design/ Sampling	Method/Tools	Study findings	Limitation
de Meneses et al. (2011) BRAZIL	To assess and compare health-related quality of life and self-esteem of patients with diabetic mellitus with and without foot ulcers.	Cross-sectional comparative study. Consecutive sampling. 20 patients without diabetic foot ulcers. 15 patients with diabetic foot ulcers.	SF-36.	The study showed that significant differences between groups were found in physical functioning. No differences in bodily pain between groups were observed. In all SF-36 domains, the mean scores for patients with foot ulcers were lower than those for patients without ulcers.	No details provided on sample size calculation. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Bradbury and Price (2011)a UNITED KINGDOM	To gain information on the number of patients attending one specialist diabetic foot clinic who experienced diabetic foot ulcer pain. To determine if relationship existed between ulcer pain and specific aetiologies of diabetic foot ulcers. To explore the type and intensity of pain experienced. To explore current management strategies being utilized.	Cross-sectional study. Consecutive sampling. 28 patients with diabetic foot ulcers.	SF-MPQ.	86% of patients reported some degree of diabetic foot ulcer pain. Pain intensity between 0-73 mm. Aching was the most common sensory pain (n=14).	Small sample size. No details provided on sample size calculation. No discussion about ethical approval from ethical committee. Limited inferential statistic applied due to sample size being small. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-MPQ; The Short-Form McGill Pain Questionnaire (Melzack 1987).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Bradbury and Price (2011) c UNITED KINGDOM	To gain information on the number of patients attending one specialist diabetic foot clinic who experienced diabetic foot ulcer pain. To determine if a relationship existed between ulcer pain and specific aetiologies of diabetic foot ulcers. To explore the type and intensity of pain experienced. To explore current management strategies being utilized. To investigate how ulcer pain impacts on quality of life.	**1st phase** Cross sectional study. Consecutive sampling. 28 patients with diabetic foot ulcers. **2nd phase** Exploratory qualitative study. Purposive sampling. 3 patients with diabetic foot ulcer pain.	**1st phase** SF-MPQ. **2nd Phase** Semi-structured interviews Interviews were recorded and manually transcribed.	**1st phase** 86% of patients reported some degree of diabetic foot ulcer pain. Pain intensity between 0-73 mm. Aching was the most common sensory pain (n=14). **2nd Phase** Four themes emerged: experience of pain; physical effects of pain; coping, psychological impact.	**1st phase** Small sample size. No details provided on sample size calculation. No discussion about ethical approval from ethical committee. Limited inferential statistics applied due to sample size was small. No discussion about validity and reliability of the study. **2nd Phase** Reflexivity aspect was not included in the article. Therefore, this aspect was not clearly understood in this study context.

Critique according to CASP (PHRU 2007); SF-MPQ; The Short-Form McGill Pain Questionnaire (Melzack 1987).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Morales et al. 2011 SPAIN	To determine the impact of foot ulcers on patients with diabetic mellitus.	Cross-sectional comparative study. Consecutive sampling. 163 patients with diabetic foot ulcer. 421 without diabetic foot ulcers.	SF-36	The study revealed that scores in subscale of physical functioning and bodily pain was lower in diabetic foot ulcer patients.	No details provided on sample size calculation. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Sanjari et al. 2011 IRAN	To describes the impact of diabetic foot ulcers on health-related quality of life.	Cross-sectional comparative study. Consecutive sampling. 54 patients with diabetic foot ulcers. 78 patients without diabetic foot ulcers.	SF-36.	The study revealed that scores in subscale of physical functioning and bodily pain was lower in diabetic foot ulcer patients.	SF-36 was generic questionnaire and does not have a special focus on diabetic foot ulcers. Sample size small. No details provided on sample size calculation. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Mazlina et al. 2011 MALAYSIA	To evaluate the impact of foot problems health-related quality of life in patients with diabetes in Malaysia.	Cross-sectional comparative study. 140 patients with foot problems. 134 patients without foot problems.	SF-36	The Sf-36 scale scores in diabetic patients with foot problems were lower. Physical functioning and bodily pain statistically significant in bodily pain among patients with foot problems.	Inclusion/exclusion criteria not specified. No discussion about sampling method. No details provided on sample size calculation. Sample size is modest. No discussion about consent from patient. Did not truly represent the general diabetes population in Malaysia as this study was taken in one diabetic clinic which was located in an urban area. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The Medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Huang et al. 2012 TAIWAN	To investigate the characteristic of diabetic patients with diabetic foot ulcers, health–related quality of life and the relationship between them.	Prospective study. Consecutive sampling. 131 patients with diabetic foot ulcers	SF-36.	The study revealed that scores in subscale of physical functioning was lower in diabetic foot ulcer patients. The study also showed statically significance in bodily pain among patients with diabetic foot ulcers ($p<0.05$).	No details provided on sample size calculation. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-36: The medical Outcomes Study 36-item Short-Form Health Survey (Ware and Sherbourne 1992).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Sibbald et al. 2011 CANADA	To evaluate the effectiveness of PHMB foam dressing compared with similar non-antimicrobial foam dressings for the treatment of superficial bacterial burden, wound-associated pain and reduction in wound size.	Randomised controlled trial. Random sampling. 23 patients with leg ulcers. 22 patients with foot ulcers. Were treated with either PHMB foam dressing or regular foam dressing without antimicrobial foam dressing, were followed up for 5 weeks.	NERDS and STONEES checklist. VAS 0-100 mm.	**Week 2** A higher proportion of subjects in the PHMB foam group (78.9%) reported no pain prior to dressing change than in the control group (33.3%). **Week 4** Pain ratings remained consistently lower, with 73.7% in the PHMB group reporting no pain versus 38.1% in the control group. **After 5 weeks** Patients treated with PHMB foam dressing reported pain was reduced compared to control group.	No details provided on sample size calculation. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); NERDS and STONEES checklist (Woo and Sibbald 2009); VAS: Visual Analogue Scale 0-100 mm; PHMB: polyhexamethylene biguanide antimicrobial foam dressing.

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Bradbury et al. 2011 UNITED KINGDOM	To evaluate the efficacy of Silvercel Non-Adherent dressing.	Case series study/ 11 patients with leg ulcers. Two patients with multiple leg ulcers. Three patients with surgical wounds. Four patients with pressure ulcers. Six patients with diabetic foot ulcers.	Pain was assessed using standardised local assessment criteria. Wounds were assessed using standardised local wound assessment criteria.	Three patients reported higher pain, which led to dressing being discontinued. One patient complained of discomfort. One patient reported that the pain had increased. One patient complained of burning sensation. Nine patients claimed that their pain was reduced. Six patients reported decreased or no pain.	No discussion about sampling method. No details provided on sample size calculation. The authors did not report at all about gaining approval from either the ethical committee or from patients. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Siersma et al. 2013 European	To identify the factors for low health-related quality of life associated with foot ulcer and the relative importance of these factors.	Cross-sectional study 1232 patients with diabetic foot ulcer.	EQ-5D.	Patients reported with poor overall health-related quality of life with main problems with mobility and pain/discomfort domain.	No discussion about sampling method. No details provided on sample size calculation. The authors did not report about gaining approval from either ethical committee or from patients. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); EQ-5D: Euro-QoL-5D (www.eurogol.org).

Table 2. 4 Summary of the studies examined the health-related quality of life in older population with diabetic foot ulcer pain (Quantitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Obilor and Adejumo 2014 NIGERIA	To determine the presence of diabetic foot ulcer-related pain and its relationship to quality of life.	Cross-sectional study. Purposive sampling. 14 patients with diabetic foot ulcers.	An adapted 37-item wound-related pain questionnaire. SF-12. VAS 0-10 cm.	All the participants experienced diabetic foot related pain at rest and during activities of daily living. Pain was significantly associated with physical functioning. General mental health and psychological well-being was significantly associated with pain during dressing change.	Small sample size. No details provided on sample size calculation. No discussion about consent from patient. No discussion about validity and reliability of the study.

Critique according to CASP (PHRU 2007); SF-12: The Medical Outcomes Study 12 -item Short-Form Health Survey (Ware et al. 1996); VAS: Visual Analogue Scale 0-10 cm

Table 2. 5 Summary of the studies examined the health – related quality of life in older population with diabetic foot ulcer pain (Qualitative)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Ashford et al. 2002 UNITED KINGDOM	To address the quality of life issues among patients with diabetic foot ulcers.	Phenomenology qualitative study. 21 patients with diabetic foot ulcers.	Semi structured interviews.	Data analysis revealed six categories of problems commonly experienced in relation to living with diabetic foot ulcers, one of which concerned pain.	Inclusion/exclusion criteria not specified. No discussion about sampling method. The authors did not reported about gaining approval from either the ethical committee or from patients. Reflexivity aspect was not included in the article. Therefore, this aspect was not clearly understood in this study context.

Critique according to CASP (PHRU 2007.

Table 2. 5 Summary of the studies examined the health – related quality of life in older population with diabetic foot ulcer pain (Qualitative) (Continued)

Author and study setting	Research aims and methodology	Research design/ Sampling	Method/Tools	Study findings	Limitation
Ribu and Wahl 2004 NORWAY	To discover the patients' perspective of living with a diabetic foot ulcers.	Exploratory qualitative study. 7 patients with diabetic foot ulcers.	In-depth recorded interviews.	Data analysis revealed six categories of problems commonly experienced in relation to living with diabetic foot ulcers, one of which concerned pain.	Inclusion/exclusion criteria not specified No discussion about sampling method Reflexivity aspect was not included in the article. Therefore, this aspect was not clearly understood in this study context.

Critique according to CASP (PHRU 2007).

Table 2. 5 Summary of the studies examined the health – related quality of life in older population with diabetic foot ulcer pain (Qualitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Miller (2006) BERMUDA	To discover the patients' perspective of living with a diabetic foot ulcers.	Phenomenology study. Purposive sampling. 6 patients with diabetic foot ulcers.	Unstructured interviews.	Data analysis revealed two themes: physical and psychological. Physical subthemes included constant care, pain, and odour. Psychological subthemes included anxiety, fears, and feeling a burden to others.	Inclusion/exclusion criteria not specified.

Critique according to CASP (PHRU 2007).

Table 2. 5 Summary of the studies examined the health – related quality of life in older population with diabetic foot ulcer pain (Qualitative) (Continued)

Author and study setting	Research aims	Research design/ Sampling	Method/Tools	Study findings	Limitation
Bradbury and Price (2011)b UNITED KINGDOM	To explore the effect of specific diabetic foot ulcer pain on life quality from the patients' perspective.	Explorative qualitative study. Purposive sampling. 3 patients with diabetic foot ulcer pain.	Semi-structured interviews. Interviews were recorded and manually transcribed.	Four themes emerged: experiences of pain, physical effects of pain, coping, psychological impact.	Reflexivity aspect was not included in the article. Therefore, this aspect was not clearly understood in this study context.

Critique according to CASP (PHRU 2007).

CHAPTER 3

METHODS

3.1 Introduction

This chapter presents an overview of the methods used to carry out the study. The discussion covers the study aim and objectives, the study design, selection of the study location, the sample selection and size, the inclusion and exclusion criteria, as well as the translation process and data collection method. Also discussed are the ethical issues regarding the research and the pilot study. The final section of the chapter clarifies the statistical methods selected to address the research questions.

3.2 Aim and objectives of the study

The aim of the present study is to investigate the relationships between diabetic foot ulcer pain and the health-related quality of life and functional status of people over sixty years in Malaysia. As stated earlier, the specific objectives and the research questions are as follows:

1. To measure the pain experiences in people over sixty years with diabetic foot ulcers in Malaysia.

- What are the pain experiences by people over sixty years with diabetic foot ulcers in Malaysia?
- What are the similarities and differences in the pain experiences between people over sixty years in Clinic S and Clinic P?

2. To measure the health-related quality of life of people over sixty years with diabetic foot ulcers in Malaysia.

- What is the health-related quality of life of people over sixty years with diabetic foot ulcers in Malaysia?
- What are the similarities and differences in the health-related quality of life between people over sixty years in Clinic S and Clinic P?

3. To measure the functional status of people over sixty years with diabetic foot ulcers in Malaysia.

- What is the functional status of people over sixty years with diabetic foot ulcers in Malaysia?
- What are the similarities and differences in the functional status between people over sixty years in Clinic S and Clinic P?

4. To investigate the relationships between pain and the selected socio-demographic and clinical characteristics, the health-related quality of life, and the functional status of people over sixty years with diabetic foot ulcers in Malaysia.

- What are the relationships between pain and the selected socio-demographic characteristic (age categories, gender, race, religion, marital status, level of education, and number of additional floors in the house), the selected clinical characteristic (duration of diabetes mellitus, number of co-morbidities, duration of foot ulcer episode, number of foot ulcer episode, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution, and type of dressing), the health-related quality of life, and the functional status of people over sixty years with diabetic foot ulcers in Malaysia?
- What are the similarities and differences in relationship between the selected socio-demographic characteristics (age categories, gender, race, religion, marital status, level of education and number of additional floors), selected clinical characteristics (duration of diabetes mellitus, number of comorbidities, duration of foot ulcer episode, number of foot-ulcer episode, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution, type of dressing), the health-related quality of life and the functional status between people over sixty years in Clinic S and Clinic P?

5. To investigate the predictors of pain in people over sixty years with diabetic foot ulcers in Malaysia.

- What are the predictors of pain among Malaysian people over sixty years with diabetic foot ulcers?

6. To examine the health care clinic use by people over sixty years with diabetic foot ulcers in Malaysia.

- How do people over sixty years with diabetic foot ulcers in Malaysia use the health care clinic?
- How do people over sixty years in Clinic S and Clinic P use the health care clinic?

3.3 Study design

The present study adopted a cross-sectional comparative survey to fulfil the research objectives. A cross-sectional design involves obtaining information from a group of people at one point in time. The process provides a “snapshot” without any attempt to follow up over time (Portney and Watkins 2009; McKenna et al. 2010). The design was considered appropriate because the investigation and measurement of pain were to be conducted at a single point of time for each participant. A longitudinal study allows investigation of a causal link between independent and outcome factors (McKenna et al. 2010). However, due to cost and time constraints, the cross-sectional design was considered suitable for this study because it generates inferences and hypotheses (McKenna et al. 2010).

Burns and Grove (2011) recommended a comparative survey design when the researcher’s intention is to describe variables in two or more groups that occur naturally in a setting. The present study was conducted in secondary and primary care clinics in Malaysia; thus, it was essential to anticipate the differences in the perception of pain in people over sixty years with diabetic foot ulcers from both clinics. Using a survey is a common research method in quantitative research. It is a quick and inexpensive method that allows the collection of significant amount of data from a sizeable population (Kelly et al. 2003; Jones and Rattray 2010). In light of these strengths, the cross-sectional comparative survey design was selected for this study.

3.4 Selection of study location

This study took place in two secondary care clinics (Clinic S) and three primary care clinics (Clinic P) in Malaysia. The secondary care clinics are situated in Kuala Lumpur (the capital of Malaysia) where the largest hospital and the biggest health care services are located. Hospital Kuala Lumpur is considered the central and the largest referral medical centre in Malaysia. The primary care clinics are located in Selangor, which has the highest population among all the states in Malaysia.

3.4.1 Justification for study location

The secondary care and primary care clinics were selected on the basis of the information obtained from the Malaysia Health Report (Ministry of Health Malaysia 2012b). The report records Kuala Lumpur and Selangor as the two states with the highest population of diabetes mellitus patients (38,399 cases in Kuala Lumpur and 128,088 cases in Selangor). This implies that patients in Kuala Lumpur and Selangor are at a higher risk of diabetes complications. It is also to be expected that the number of diabetic foot ulcer patients will increase substantially in these areas.

Moreover, as a tertiary referral centre, Kuala Lumpur Hospital receives many people with diabetic foot ulcers from different regions in Malaysia (from both rural and urban areas). These patients have varied socio-economic, cultural, and educational backgrounds, and they often seek to get inpatient and/or outpatient management. Hence, they represent a cross-section of the population and thus, will allow generalisation of the study results. This advantage is further strengthened by the Wound Care Unit, established in 2013, which operates primarily as the central reference for all chronic wound patients, particularly those with diabetic foot ulcers, from hospitals throughout Malaysia.

3.5 Sample selection and size

3.5.1 Sampling

A target population is a complete set of individuals who have the characteristics that the researcher is interested in studying, and to whom the researcher intends to generalize the findings (Nieswiadomy 2008; Portney and Watkins 2009). The target population in this study is people over sixty years with diabetic foot ulcers in Malaysia. However, it was not reasonable to recruit all the people over sixty years with diabetic foot ulcers from across the country or from one region. For this reason, a study population was used (Procter et al. 2010). In the present study, the study population is a subset of the target population from whom an accessible sample was taken over the six-month period of data collection on the basis of specific inclusion criteria. The important consideration about sampling in a quantitative study is to get a sample that is representative of the target population (Portney and Watkins 2009). The preferred sampling technique for a quantitative study is probability sampling, but when the sampling frame from which the sample will be drawn is incomplete, nonprobability sampling is considered (Jirojwong et al. 2014).

This study adopted a consecutive sampling technique. The sampling method recruits participants continuously from an easily reached population who meet the eligibility criteria over a specified period of time or until a particular sample size is reached (Polit and Beck 2012). Based on this definition, all patients with diabetic foot ulcers who met the inclusion criteria were approached. A consecutive sampling method is considered the best and the most practical technique of nonprobability sampling because the sample will eventually represent the entire population (Polit and Beck 2012).

3.5.2 Sample size

In quantitative research, a large number of participants are needed to ascertain the characteristics and be representative of the population (Kelly et al. 2003). To obtain a large enough sample size in the survey, the specification of the sample size should be considered, and a power analysis needs to be performed to estimate the necessary number of participants (Polit and Beck 2012). In the

case of Malaysia, there have been a limited number of epidemiological studies on diabetic foot ulcers, and no reliable estimate of prevalence could be traced. This is probably because Malaysia's population is composed of various ethnic groups: about 23% the population are Chinese, 7% are Indian, other ethnic groups comprise 10% of the population, and the remainder are of the Malay ethnicity (Department of Statistics Malaysia 2010). The risk of developing diabetes and diabetic foot ulcers varies with ethnicity.

Following a discussion with an epidemiologist and with staff employed in the clinical areas, a pragmatic approach was taken on the basis of the number of people likely to be available to take part in the study, allowing for withdrawals. In conclusion, a sample of 300 was needed for the study.

3.6 Inclusion and exclusion criteria

There were five inclusion criteria for the study:

1. Patients diagnosed with diabetes mellitus type 1 or 2.
2. Patients diagnosed with diabetic foot ulcers.
3. Patients aged 60 and above.
4. Patients with the ability to answer the questions in English or Malay.
5. Patients who were willing to take part in the study.

The exclusion criteria for this study were as follows:

1. Patients below 60 years of age.
2. Patients who were not willing to take part in the study.

The above criteria were set in order to recruit a potential representative sample of people with diabetic foot ulcers. Patients were invited to participate in this study if they had been diagnosed with diabetic mellitus type 1 or 2 and diabetic foot ulcers. Furthermore, this study aimed to investigate the relationships between diabetic foot ulcer pain and the health-related quality of life and functional status of people over sixty years; therefore, the patients could be recruited only if they were aged 60 years or older.

In addition, the interviews in this study were going to be conducted solely by the researcher, who is able to communicate only in Malay and English. Given this

point, the patients were recruited if they were able to understand and communicate in Malay or English, or both.

Patients with diabetic foot ulcers were excluded from this study if they were less than 60 years old at the time of the study and if they were not interested in participating in the study.

3.7 Data collection

3.7.1 Questionnaire

For this study, questionnaires were used to investigate the relationships between diabetic foot ulcer pain and health-related quality of life and functional status in people over sixty years. The four most commonly adopted modes for collecting data for questionnaire-based surveys are (1) self-administered questionnaire, (2) telephone interview, (3) interviewer-administered questionnaire, and (4) online methods including web-based questionnaire.

The ideal method for data collection is the self-administered questionnaire because the results can be collected from a large number of participants. However, the interviewer-administered questionnaire was the primary instrument used for data collection in this study. Through this method, the questionnaire was read out to the participants by the researcher, who filled out all the answers in the questionnaires herself. The purpose of the interviewer-administered questionnaire was to encourage more patients to participate in the survey and to increase the response rate. This technique also provided opportunities for the researcher to clarify any questions that were unclear to the participants (Jirojwong et al. 2014). From the researcher's experience, older patients prefer questions to be read to them. Nevertheless, the participants were also given the option to complete the questionnaire with help from their relatives who accompanied them for the treatments. Two participants asked to complete the questionnaire by themselves. In this case, to avoid problems of incomplete questionnaires and missing data, the participants were asked to return their questionnaires personally to the researcher. The questionnaires were then checked on the spot by the researcher and the participants were asked to complete information that might be missing.

3.7.2 Instruments

To better account for the impacts of diabetic foot ulcer pain, a number of research instruments were developed to examine the relationships between pain and health-related quality of life and functional status of people over sixty years with diabetic foot ulcers in Malaysia. The complete questionnaire was tested in a pilot study (see Section 3.15). Details of the questionnaire are provided in A 4.1 (English version) and A 4.2 (Malay version) of Appendix 4.

A summary of the instruments and sources of data are outlined in Table 3.1.

Table 3. 1 Summary of instruments and sources of data used to access pain, health-related quality of life and functional status in older people with diabetic foot ulcers in Malaysia

Instruments	People over sixty years	Medical records
Demographic data	/✓	/✓
Clinical data and the health care clinic use	/✓	/✓
The short-form McGill pain questionnaire (SF-MPQ)	/✓	
The medical outcomes study 36-item short-form health survey (SF-36)	✓/	
Diabetic foot ulcer scale – short- form (DFS-SF)	✓/	
Katz activities of daily living (Katz ADL)	✓/	
Lawton instrumental activities of daily living (Lawton IADL)	✓/	

3.7.2.1 Socio-demographic data

To establish the representativeness of the sample, a range of background data was obtained. The participants were required to supply information on their age, gender, ethnicity, religion, current marital status, completed educational level, and number of additional floors in the house. The data were collected from the patients themselves.

3.7.2.2 Clinical data and health-care clinic use by people over sixty years with diabetic foot ulcers

This section is divided into two parts. The first part is concerned with the participants' clinical data such as number of foot ulcer episodes, site of foot ulcer, frequency of dressing change, type of cleaning solution, type of dressing, severity of foot ulcer, and surgical intervention or procedure. The data were

collected from the patients' medical notes. However, it was found that the medical notes for many of the patients were neither organised nor complete, particularly for those attending the primary care clinics. Therefore, information about the duration of diabetic mellitus, duration of foot ulcer episode, number of co-morbidities, and the perceived cause of diabetic foot ulcers was obtained either from the patients themselves or from the medical notes. On the other hand, information on treatment-related instruction/methods and the use of analgesia was obtained through the patients' self-reports.

The second part of this section consists of questions on health care clinic use by people over sixty years with diabetic foot ulcers, such as information on diabetic foot ulcer pain control as well on as the people responsible for providing information on diabetic foot ulcer pain control to the patients.

Satisfaction with the health services was measured by asking the following question: "How satisfied have you been so far with the care that you have received for your wound in the health care clinic?" The patient was required to rate their answer using a six-point scale: "very satisfied", "satisfied", "somewhat satisfied", "somewhat dissatisfied", and "very dissatisfied".

One open question regarding the people over sixty years's comments or suggestions to improve the quality of health services at the clinic was also included in this section.

3.7.2.3 The short- form– McGill pain questionnaire

A number of pain scales were considered in order to decide the most appropriate scale to be used. Two scales were then selected for consideration: the McGill pain questionnaire and the SF-MPQ.

The McGill pain questionnaire was developed by Melzack in 1975 for assessing chronic pain. The questionnaire provides an elegant measure of the sensory, affective, and evaluative aspects of a pain experience based on the gate–control theory (Melzack 1987). The McGill pain questionnaire was excluded because it is too lengthy, and patients may have found answering the questions complicated.

The Melzack's questionnaire was modified to the SF-MPQ in 1987, and the revised version was used to evaluate pain in this study. In the present study, the SF-MPQ incorporates fourteen pain descriptors that form the pain rating index (PRI). The participants were asked to rate each descriptor on a 4-point intensity scale (0=none, 1=mild, 2=moderate, 3=severe). Ten descriptors were used to assess the sensory dimension of the pain experience, and the remaining four descriptors were used to assess the affective dimension. The PRI subscales were summed to acquire the scores for sensory (PRI-Sensory), affective (PRI-Affective), and total (PRI-Total) from 0-33, 0-12, and 0-45 respectively. The SF-MPQ also includes a 100-mm VAS, and the present pain index (PPI) is a 5-point intensity scale that ranges from 0 = mild to 5 = excruciating (Melzack 1987).

The scale has been found to be valid, reliable, and reproducible for a variety of acute and chronic conditions. The Cronbach's alpha coefficient for the subscales and the total scales has been shown to range from 0.73 to 0.89 (Hawker et al. 2011).

The SF-MPQ is a generic tool that has been shown to be valid and reliable in several different patient populations (McDonald and Weiskopf 2001). The questionnaire has also been proved to be easy to use by patients (Melzack 1987). Additionally, the tool has been shown to correlate well with the original longer version of the McGill pain questionnaire and is suitable for use in research because it is less time consuming to complete (Melzack 1987). The questionnaire has not been directly validated for use in patients with chronic wounds, but a study by Bradbury and Price (2011a) and Bradbury and Price (2011c) among diabetic foot ulcer patients reported that out of twenty-eight patients, twenty-four patients reported diabetic foot ulcer pain, and that the most frequently used pain descriptor in the SF-MPQ was "aching" followed by other descriptors such as "throbbing," "hot-burning," and "tender."

This assessment tool was selected for its ability to capture the sensory and affective aspects of pain as well as the intensity of pain. This point was felt to be useful because it can facilitate identifying if certain pain characteristics are associated with diabetic foot ulcers and in understanding the experience of having diabetic foot ulcer pain. Moreover, because minimal studies have been

conducted on diabetic foot ulcer pain, especially in Malaysia, there was no indication within the literature as to the most suitable assessment tool for measuring diabetic foot ulcer pain. The SF-MPQ was therefore considered the best generic tool available to provide detailed information on experiences of diabetic foot ulcer pain (Bradbury and Price 2011a; Bradbury and Price 2011c). The tool is also well suited for an older population; it is (1) comprehensive, quick, and easy to administer; (2) easily understood by patients; (3) simple to score, and (4) able to measure the sensory and affective components of pain. Besides, the Malay version of the SF-MPQ has been translated and validated by a group of researchers from one of the pharmaceutical companies in Malaysia. Permission to use the SF-MPQ was obtained from the Mapi Research Trust and is provided in Appendix 2 of licence A 2.1.

3.7.2.4 Health-related quality of life questionnaire

Advances in medicine have expanded the focus of healthcare from only extending life to also include improving the quality of life. The World Health Organisation quality of life Group (WHOQOL-G) defined quality of life as the "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, values and concerns" (1998, p. 551). WHOQOL-G acknowledges that peoples' perceptions about their life are subjective, shaped by their cultural background, life experiences, preferences and personal objectives. Therefore, the quality of life is a dynamic concept due to the fact that values and evaluations of life are influenced by an individual's reactions, emotions, physical health status and/or experiences (Carr et al. 2003). It is also a multidimensional term that reflects the individual's overall lives (Bowling 2001). Health-related quality of life narrows the scope of quality of life and focuses specifically on the impact of illness and treatments on a person's life (Bowling 2001). Bowling (2001) defined health-related quality of life as "an optimum level of mental, physical, role (e.g. work, parent, career, etc.) and social functioning, including relationships, and perceptions of health, fitness, life satisfaction and well-being. It should also include some assessment of the patient's level of satisfaction with treatment, outcome and health status and with future prospects" (p. 6). Thus, the primary focus of this thesis is on the health-related quality of life, as health-related

quality of life is a more specific term, and refers to the way people feel about their physical as well as mental health.

The acute and chronic complications of diabetes such as neuropathy, nephropathy, and retinopathy are the most commonly diagnosed in patients. As a consequence of a poor control of diabetes, there is a high potential for to have heart disease, blindness, sexual dysfunction and circulatory problems in addition to other complications (Darvishpoor and Abed 2013). Darvishpoor et al. (2005) claimed that the burden of disease management of diabetes mellitus; complex and expensive therapeutic regimens; dietary restrictions; the need to have insulin injections; as well as having blood and urine tests would drastically impair one's quality of life. Previous studies assessing the effect of diabetes mellitus on health-related quality of life have been carried out in a number of countries; and the results have shown that there is a decrease in the health-related quality of life among diabetes mellitus patients as reflected in the SF-36 scale scores (Ahola et al. 2010; Darvishpoor and Abed 2013; Basir et al. 2016). This is further strengthened by Basir et al. (2016) who found that the health-related quality of life in the SF-36 scores were poorer in diabetes mellitus patients as compared to the general population, particularly in the physical domains and is less pronounced in the mental domains. As such, diabetes mellitus may have an impact on patients' physical, psychological and social functioning that consequently altered their health-related quality of life, therefore, it is particularly interesting to assess the health-related quality of life in these patients.

Tenval and Apelqist (2000) mentioned that measuring the health-related quality of life involves generic and disease-specific instruments. Both the instruments used in this study, such as the SF-36 and DFS-SF are generic and disease-specific instruments. However, while the SF-36 can be considered a generic instrument that allows comparison with other instruments because it involves the use of measures that are appropriate across health and illness groups (Giplin and Lagan 2008), the DFS-SF is considered a disease-specific instrument that can provide greater description of the disorder's characteristics as well as the related physical, emotional, and social functions (Reiber et al. 1998).

The researcher decided to use both instruments as recommended by Giplin and Lagan (2008) because the combination of a generic and a disease-specific instrument will provide useful indication of a person's outcome while considering changes in a treatment regimen.

3.7.2.4.1 The medical outcomes study 36- item short-form health survey (SF-36)

The generic health-related quality of life was measured using the SF-36. The SF-36 comprises thirty-six items covering eight domains that target the physical measures summary (PCS) and the mental measures coefficient (MCS) (Ware and Sherbourne 1992). The goal when constructing the scales included in the SF-36 was to achieve comprehensiveness with the representation of multidimensional health concepts, including the levels of well-being and personal evaluation of health (Ware and Sherbourne 1992). It has been validated and proven to be a reliable generic instrument to comprehensively measure health-related quality of life. Furthermore, the SF-36 has shown sensitivity when correlating health-related quality of life scores with diabetic foot ulcers (Ribu et al. 2007).

The SF-36 measures eight domains: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality/energy (VT), social functioning (SF), role emotional (RE), and mental health (MH).

Version 2 of the SF-36 (SF-36v2) enables norm-based scoring for health-related quality of life in the general population. The main advantage of the SF-36v2 is that the norm-based scoring makes the interpretation of research results easier than those obtainable with the previous version. The mean was set at 50, and the standard deviation was set at 10 (Ware 2000). The scores on each domain ranged from a minimum of 0 to a maximum of 100. Better health components are indicated with the increase in the scores.

The reason for choosing the SF-36 was that the questionnaire had been used in the Malaysian secondary care and primary care clinics in previous studies. The literature review uncovered that the SF-36 is the most common instrument used for determining the quality of life within Malaysian populations. The SF-36 has already been translated and validated in Malaysia by Sararaks et al. (2005), and

there are samples of published studies conducted in Malaysia which had used the instrument. Because the instrument has been translated, validated, and used in the Malaysian context, it was appropriate for the researcher to use it in the present study. Permission and license to use the SF-36 was obtained from Quality Metrics Incorporated, U.S.A. (Lincoln, RI, USA) and is provided in Appendix 2 of licence A 2.2.

3.7.2.4.2 Diabetic foot ulcer scale – short- form (DFS-SF)

The Diabetic foot scale short form (DFS-SF) is a shorter version of the DFS, consisting of only twenty-nine items. The questionnaire has been used to assess the relationships between foot ulceration and health-related quality of life. It was derived from the DFS by removing items that showed poor psychometric properties, and a new subscale was developed using exploratory factor analyses. The DFS-SF comprises six scales: “leisure”, “dependence/daily life”, “negative emotions”, “physical health”, “worried about ulcers/feet,” and “bothered by ulcer care.”

Bann et al. (2003) mentioned that the test-retest reliability of the DFS-SF was examined in a clinical trial, where the DFS-SF was repeatedly administered over a four-week period. The intra-class correlation coefficient (ICC) was 0.57 for leisure, 0.61 for physical health, 0.77 for dependence/daily life, 0.64 for negative emotions, 0.54 for worried about ulcers/feet, and 0.59 for bothered by ulcer care, which appeared to be reasonable. Furthermore, the internal consistency of the DFS-SF was good, with the Cronbach’s alpha coefficient ranging from 0.80 for the bothered by ulcer care scale to 0.95 for the negative emotions scale (Bann et al. 2003). Construct validity was also confirmed by a multitrait-multimethod matrix. To be more specific, the DFS-SF physical health scale correlated more with the vitality scales of SF-36 (r = 0.63) than with the scales hypothesised as unrelated, such as the role emotional scale of SF-36 (r = 0.35). Moreover, as hypothesised, the DFS-SF leisure scale was moderately correlated with the social functioning scale of SF-36 (r = 0.56). The sensitivity of the DFS-SF scales was also demonstrated, with patients who had a completely healed target ulcer recording significantly higher scores on the leisure, negative emotions, and worried about ulcers/feet scales compared to patients who had not experienced the same.

The stability of the six-scale structure of the DFS-SF was examined by replicating an exploratory factor analysis on two samples (Bann et al. 2003). The DFS-SF factor structure was highly stable across the two samples with the coefficients of congruence as 0.79 for leisure, 0.90 for dependence/daily life, 0.88 for worried about ulcers/feet, and 0.95 for bothered by ulcer care. Scorings of the DFS-SF scales are calculated by the following equation: Score = [(sum-min)/range] x 100, where sum is the sum of the raw item scores, min is the minimum possible sum of item scores, and range of the sum of item scores (Bann et al. 2003). Higher values indicate a better quality of life.

The DFS-SF has only been recently developed, and because of its short nature and good psychometrics, it appeared to be more appropriate and preferable than the DFS instrument (Bann et al. 2003). In Malaysia, there is so far no evidence of its having been used with diabetic foot ulcer patients. However, due to its brevity and simplicity, it could be worthwhile using this questionnaire in the Malaysian primary care setting. Moreover, with only twenty-nine questions, the DFS-SF was more convenient particularly for use with older people, as they may have difficulty interacting with long and difficult questions. Permission to use the DFS-SF was obtained from the Mapi Research Trust and is provided in Appendix 2 of licence A 2.3. The DFS-SF was not available in the Malay language. Therefore, the DFS-SF underwent a forward-backward translation process (see section 3.8).

3.7.2.5 Functional status questionnaire

A functional status is an individual's ability to perform the normal daily activities required to meet basic needs, play their usual roles, as well as maintain health and well-being (Leidy 1994). Old age is generally accompanied by frailty, proneness to illness and the experience of physical discomfort, which may prevent people from conducting tasks independently in their daily lives (Hairi et al. 2010). As mentioned in Chapter 1, older people are at risk of developing chronic NCDs such as hypertension, diabetes mellitus, and hyperdyslipidemia.

The negative effects of diabetes may either be directly related to the disease itself or through its associated complications. Older population with diabetes mellitus whose functional status is already declining due to aging is further

affected by the presence of complications associated with diabetes such as neuropathy, nephropathy, and retinopathy. There are a number of previous studies which have shown a reduction in physical function and health status in older patients with diabetes (Gregg et al. 2002; Sinclair et al. 2008; Bossoni et al. 2008). For instance, Sinclair et al. (2008) have reported that diabetic patients aged 65 years and older have limitations while performing activities of daily living and instrumental activities of daily living. It is therefore important to recognize the impact of diabetes complications on top of the functional decline which is known to occur in older people.

As the participants of this study were those patients with diabetic foot ulcers aged 60 years or over, consideration was also given to age-related changes in functional status changes and the use of a functional status instrument. The functional status level was evaluated with the Katz ADL and Lawton IADL. Both instruments were chosen for their age-related nature. The Katz ADL was designed to measure physical functioning, such as bathing, dressing, transferring, toileting, continence and feeding while the Lawton IADL was designed to measure a higher level of physical functioning than that of the index of ADL, such as travelling, shopping, preparing meals, doing housework and managing medications, using the telephone as well as managing money. Thus, the decision to use both the Katz ADL and the Lawton IADL was appropriate, as they can be considered to complement each other, and both are suitable for samples aged 60 years or over.

3.7.2.5.1 Katz activities of daily living (Katz ADL)

The Katz ADL was developed to measure physical functioning of the elderly who are chronically ill. Katz and Akpom (1976) developed a screening tool to measure independent ability within six areas: bathing, dressing, transferring, toileting, continence, and feeding among older people.

The scale was scored per item as *0 = independent* and *1 = dependent*. The total score ranged from 0 (total independence) to 6 (total dependence).

This index has been found to be valid to evaluate functional assessment in culturally diverse elderly people. The Cronbach's alpha coefficient has been

shown to range from 0.84 to 0.94 in a sample of 304 Dutch, 330 Turkish, and 229 Morocons elderly (Reijneveld et al. 2007).

The fact that this instrument is used extensively and is recommended by the Hartford Institute for Geriatric Nursing suggests that it is a useful and appropriate measure of this variable (Shelkey and Wallace 1998). Permission to use the Katz ADL was sought from the Oxford University Press and is provided in Appendix 2 of licence A 2.4. The Katz ADL was not available in the Malay language. Therefore, the Katz ADL underwent a forward-backward translation process (see section 3.8).

3.7.2.5.2 Lawton instrumental activities of daily living (Lawton IADL)

The instrumental activities of daily living (IADL) scale (Lawton and Brody 1969) is designed to measure a higher level of physical functioning than that of the index of ADL, particularly for community populations with lower levels of disability. The scale has seven items measuring independence in activities such as travelling, shopping, preparing meals, housework and managing medications, using the telephone' and managing money. The total score ranges from 0 to 8.

Lawton and Brody (1969) tested the scale on 265 older people and reported a Guttman reproducibility coefficient of 0.96 for the Physical Self-maintenance (PSM) Scale and 0.93 for the IADL Scale. The validity was demonstrated by the correlations between the scale and the Physical Classification (PC), the Mental Status Questionnaire (MSQ), and the Behavior and Adjustment rating scales (BA). Permission to use the Lawton IADL was sought from the Oxford University Press and is provided in Appendix 2 of licence A 2.4. As the Lawton IADL is not available in the Malay language, it underwent a forward-backward translation process (see section 3.8).

3.8 Translating the questionnaires

The three questionnaires selected for the study – the DFS-SF, the Katz ADL, and the Lawton IADL questionnaire – were not available in the Malay language. Therefore, the questionnaires had to be translated. There are three approved

types of translation methods in translating a cross-cultural research instrument, namely, one-way translation, forward and backward translation, and the committee approach. These approaches are highly recommended by cross-cultural researchers.

In this study, as mentioned previously, the forward-backward translation method was adopted to translate the DFS-SF, Katz ADL, and Lawton IADL questionnaires. This method requires at least two translators to work independently. The first translator translates the original instrument into the required language, and later, the second translator translates the translated version back into the original language (Hilton and Skrutkowski 2002).

To avoid some inherent translation problems, the questionnaires were translated following the guidelines by the Mapi Research Trust.

The translation process of the questionnaire adhered to the following steps:

1. Permission to translate the questionnaire
2. Forward translation
3. Reconciliation
4. Back translation
5. Back translation review
6. Cognitive debriefing
7. Proofreading and finalization

3.8.1 Permission to translate the questionnaire

Prior to translating the questionnaire, the researcher contacted the Mapi Research Trust (the copyright holder of the English DFS-SF) and the Oxford University Press (the copyright holder of Katz ADL and the Lawton IADL) to seek permission to translate the questionnaires into the Malay language. After permission had been obtained, the process of forward and backward translation was initiated.

3.8.2 Forward translation

The forward translation process was carried out by two nursing lecturers. The first translator was a nursing lecturer who was an expert in community health and orthopaedic. She was responsible for translating the English version of the DFS-SF to the Malay language (T1a). The other translator responsible for translating the English version of the Katz ADL (T1b) and the Lawton IADL (T1c) to the Malay language was a lecturer in medical and gerontology nursing. Another translator was an English lecturer; she translated the English versions of DFS-SF (T2a), Katz ADL (T2b), and Lawton IADL (T2c) into the Malay language. These individuals were selected for their professional skills and research knowledge as well as for their expertise in both English and Malay languages.

3.8.3 Reconciliation

The questionnaires were the reviewed by the translators and the researcher. Discrepancies amongst the different versions of the questionnaires were identified and resolved. The process produced the Malay versions of DFS-SF version B, Katz ADL version B, and Lawton IADL version B.

3.8.4 Back translation

The consensus Malay versions for the DFS-SF, Katz ADL, and Lawton IADL were translated back into English by a bilingual English teacher. She had worked as an English teacher for more than ten years and was experienced in translation procedures. She was not provided with the original version of the DFS-SF, Katz ADL, and the Lawton IADL to avoid biasedness in her back-translation.

3.8.5 Back translation review

The researcher then reviewed the back translation against the original English version of the DFS-SF, Katz ADL, and Lawton IADL. The researcher identified a number of problematic items and refined the agreed DFS-SF version B, Katz ADL version B, and Lawton IADL version B in order to maintain the conceptual

equivalence of the translation. However, no modifications were made on the consensus version. This process then produced the Malay versions of DFS-SF version C, Katz ADL version C, and Lawton IADL version C.

Then, the questionnaires were submitted to the expert panels. They were invited to offer input regarding the translation. The selection of these experts was based on their personal characteristics and other credentials.

A university lecturer, who specialises in community health and health promotion, was selected due to the subject of her PhD being very closely related to the topic of diabetes mellitus and older people. She was given the responsibility of reviewing the Malay version of DFS-SF version C. She proposed some modifications to improve the clarity of the translation. Details of the suggestions are shown in Table 3.2. With that, the Malay version of DFS-SF version D was created.

The Malay versions of Katz ADL version C and Lawton IADL version C were given to an occupational therapist with experience in geriatric rehabilitation in a clinical setting. The therapist held a master's degree in occupational therapy and was also a university lecturer specialising in gerontology.

The lecturer and the occupational therapist were selected for their familiarity with the target population; they had experience working with older people. Furthermore, the Katz ADL and the Lawton IADL questionnaires were designed specifically for older people, and both panels were familiar in dealing with this age group. The Malay version of Katz ADL version C and Lawton IADL version C were reviewed, and no further modification was made. It was concluded that the questionnaire had good face and content validity in measuring the functional status among people over sixty years in Malaysia. With that, the Malay versions of Katz ADL version D and Lawton IADL version D were developed.

Table 3. 2 Suggestion modification by panel.

Item	Original English version	Malay DFS-SF version C	Suggestion changes made by panel were underlined
1d	Made you choose a different kind of holiday or short break than you would have preferred	Menyebabkan anda terpaksa memilih percutian yang lain daripada kegemaran biasa anda.	Membuatkan anda terpaksa memilih percutian yang lain daripada kegemaran biasa anda.
1e	Meant that you had to spend more time planning and organising for leisure activities.	Membuatkan anda perlu meluangkan lebih masa untuk merancang dan menyusunatur aktiviti percutian anda	Bermaksud anda perlu meluangkan lebih masa untuk merancang dan menyusunatur aktiviti percutian anda
3e	Felt that doing anything took longer than you would have liked	Merasakan setiap perbuatan anda seolah-olah lebih lama untuk dihabiskan daripada biasa	Merasakan setiap perbuatan anda seolah-olah memerlukan lebih lama untuk dihabiskan daripada biasa.

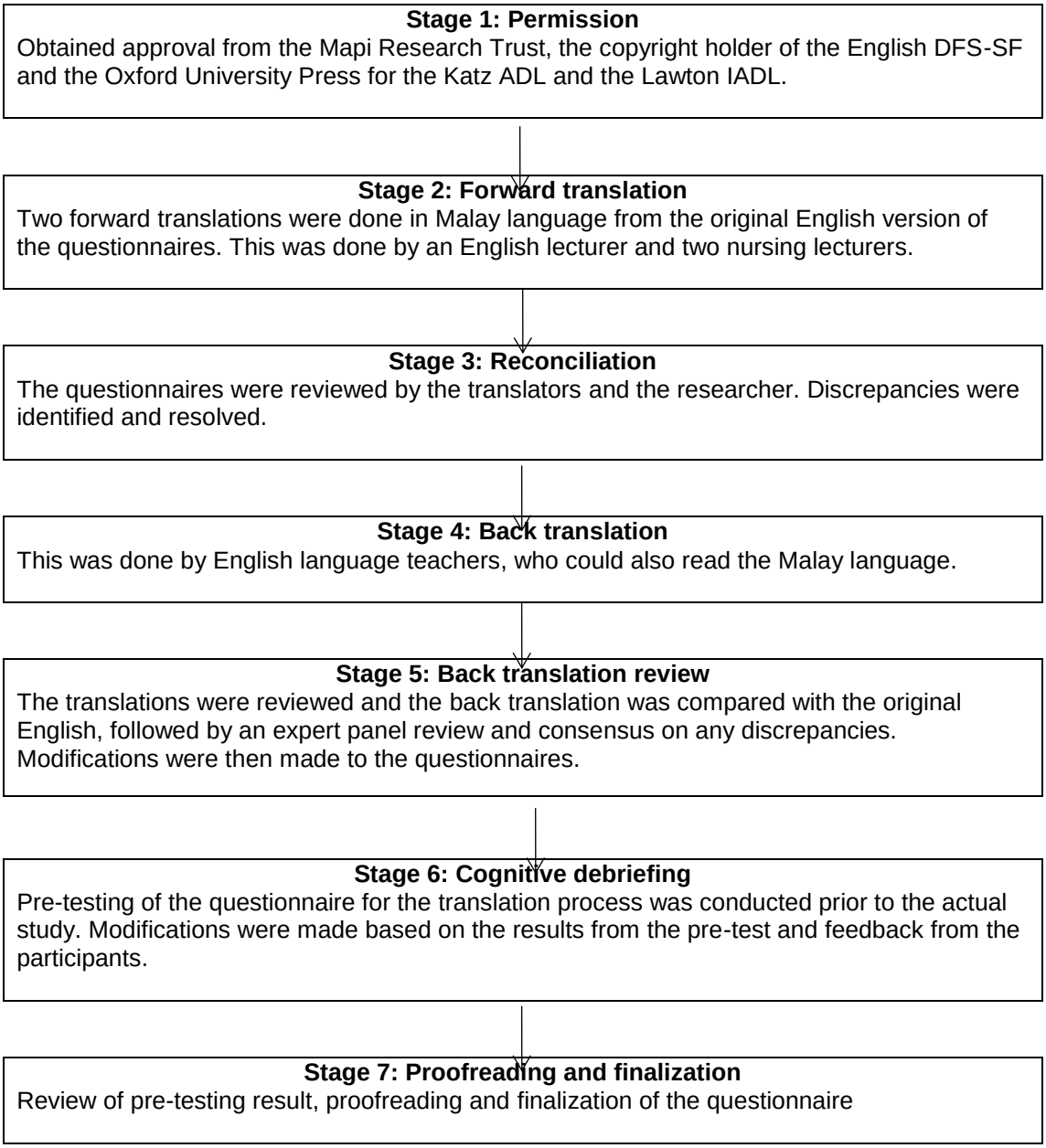
3.8.6 Cognitive debriefing

To assess the clarity, intelligibility, and appropriateness relevance of the Malay version of the questionnaire in patients with diabetic foot ulcers, pre-tests were performed at two of the participating clinics. A group of six people piloted the Malay version of the questionnaire. They were requested to comment on items they found difficult, upsetting, or confusing. The results showed that all six patients understood and were able to complete the Malay version of the DFS-SF, the Katz ADL, and the Lawton IADL questions. Only one female participant did not understand the meaning of “ulcer” in the DFS-SF questionnaire. She particularly asked whether “ulcer” referred to “cut” in English, but since this questionnaire focuses on diabetic foot ulcers and not “cuts,” no further modification was made.

3.8.7 Proofreading and finalization

At the end of the whole process, it was the researcher who finalised the translation and did the final proofreading. With that, the final Malay versions of the DFS-SF, Katz ADL, and Malay Lawton IADL were formed.

Figure 3. 1 Stages in the translation and back-translation process of questionnaire



3.9 Process of gaining access

Gaining access into the research site is considered a crucial step in carrying out any research (Creswell 2007). In the present study, the process began by contacting the Ministry of Health Malaysia, the director of the hospital (for access to secondary care clinics), and the director of public health (for access to primary health clinics). These people were identified as the main gatekeepers of the sites. Upon agreement being received from the directors, an invitation letter that provided a brief explanation about the study was sent to the heads of department and heads of the respective clinics. The respective heads of department and heads of clinic were requested to complete a reply stating their agreement for the study to be conducted in their clinics. To increase the chances of being granted access, the researcher met with each respective department head personally to provide a detailed explanation of the study. The meetings also served as a platform for the researcher to assure the heads of department that there would be no interruption to the routines and activities within the sites, and that they would be given evidence-based suggestions at the end of the study to improve their current practice. Each of the clinics approached agreed to participate in the study.

The process of recruiting participants commenced upon the receipt of approval and agreement from the Government of Malaysia, the Ministry of Health, the directors of the hospital and public health, the heads of department and the heads of the clinics. (see A 3.2 and A 3.7 of the Appendix 3).

3.10 Recruitment procedure

The process used to recruit people over sixty years with diabetic foot ulcers was discussed with nurse managers, nurses, and clinic administrators. The purpose of this discussion was to gain their cooperation in identifying potential participants. The aspects discussed included routine activities of the clinic, number of patients with diabetic foot ulcers who attended the clinic, inclusion and exclusion criteria, and the best way to approach the patients. Initially, the researcher decided to compile a list of patients' names one day before the consultation in order to recruit all eligible patients systematically. However, according to one nurse manager, the strategy could be inappropriate because

sometimes, new cases are seen without prior appointments, and some patients may cancel their consultations or dressing procedures. The appropriate recruitment strategy having been discussed with the staff, it was decided that the researcher should make herself available in the clinic and that the nurses as well as the clinic administrators would introduce her to eligible patients. This strategy was adopted to ensure that the researcher would have the information about the eligible patients attending the clinic on that particular day and as few patients as possible would be missed.

The participants who agreed to participate were interviewed before the dressing procedure or the consultation session at the clinic. It was the researcher's intention to have all the participants interviewed prior to their consultation and/or dressing procedures because any news about their progress or information on undesired health conditions may have affected the participants' perception and may have resulted in biasedness in their report on pain perception.

At the beginning of the study, the researcher's intention was to recruit older patients, that is, aged 65 years and above. However, during the pilot study, it was discovered that the majority of the patients diagnosed with diabetic foot ulcers were aged 60 years and above. Further discussions with the heads of department and nurse managers were conducted, and the supervisors were informed about this finding. A final decision was made to include patients aged 60 years and above to ensure that an adequate sample was achieved. Furthermore, in Malaysia, older persons are defined as those who are aged 60 years and above.

3.11 Data collection procedure

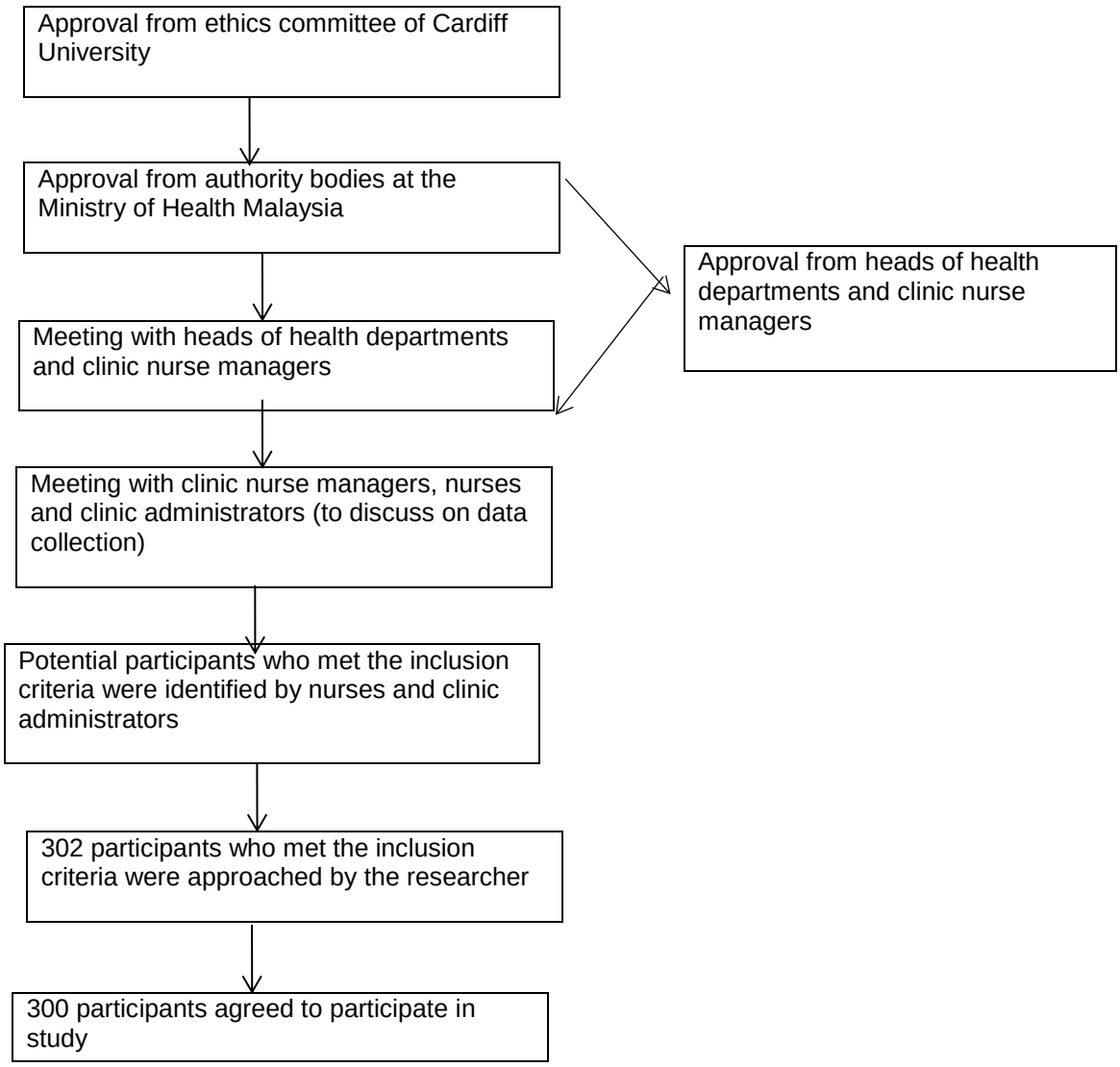
The procedure for the data collection was as follows:

- Potential participants who met the inclusion criteria were identified during their registration at the counter. The researcher introduced herself to the potential participants and inquired if they were willing to participate in the study. If they agreed, the researcher then took them to a private room for the interview session.

- In the private room, the researcher explained to the patient about the study following the information sheet. This was followed by explaining the method and process of the study. The patient was assured that his or her identity would be kept confidential. Patients were also informed that the results obtained from the study were strictly for research purposes and that they had the right to withdraw from the study at any time.
- The participants who agreed to participate signed the consent form. Once they had given their agreement, the researcher then read the questions to each participant face-to-face while completing all the information on the questionnaires. The participants were also given the option to complete the questionnaire with help from their relatives.
- A small souvenir from the researcher (a towel) as a token of appreciation was given to each of the participants. Handling out gifts is a cultural practice among Malaysians, and it is a way of expressing one's gratitude.
- Participants who had already answered the questionnaire once were not sampled again if they returned to the clinic during the study duration.

Figure 3.2 sums up the research procedures.

Figure 3. 2 Flow chart of the research procedures



3.12 Ethical Approval and Ethical Considerations

The following discussion summarises the ethical considerations addressed in this study relating to the patient population. Most ethical issues in this study relate to (1) research governance and ethical approval, (2) informed consent and voluntary participation, (3) beneficence and nonmaleficence, as well as (4) anonymity and confidentiality.

3.12.1 Research governance and ethical approval

Prior to accessing the participants and starting the fieldwork, the researcher obtained ethical approval from the School of Healthcare Sciences, Cardiff University Ethical Committee, and the Malaysia National Medical Research

Register (NMRR). The process began after the research proposal had been examined and approved by the supervisory team. Once approval had been obtained from the School of Healthcare Sciences, Cardiff University Ethical Committee, permission to conduct data collection in Malaysian healthcare organizations was sought from the Malaysia Ministry of Health, Director of Kuala Lumpur Hospital, Director of the Health Department of the Federal Territory of Kuala Lumpur and Putrajaya, Director of the Health Department of the Selangor as well as the heads of the departments involved (see A 3.1 to A 3.7 of the Appendix 3). Ethical approval from the Malaysian Medical Research Ethical Committee was also sought (see A 3.8 of the Appendix 3). The data collection activities began only after permission had been obtained from all the authorities and bodies above.

3.12.2 Informed consent and voluntary participation

Informed and voluntary consent is defined as an explicit agreement given by research participants without any threat or inducement (Holloway and Wheeler 2010). In providing agreement, participants need to be adequately informed about the research. They also need to comprehend the information and have the power of freedom of choice that enables them to decide whether to participate in the study (Polit and Beck 2012).

To avoid any misunderstanding about the study, the patient information sheet and the consent form were written in both Malay and English. The patient information sheet provided a description of the study and was given to the participants according to their language preference. They were also given the option of reading it themselves or of having the researcher read it to them prior to them giving their consent to be part of the study. The same applied to the consent form: the participants would sign it in the language they preferred, either by reading it themselves or by having it read to them by the researcher (see A 4.3 to A 4.6 of the Appendix 3).

The name and contact details (phone number and email address) of the researcher and her supervisors as well as of the School of Healthcare Sciences, Cardiff University Ethical Committee, and the NMRR were included in the patient information sheet. With the contact information, the participants were

able to contact the researcher to discuss any concerns or issues during the study period.

3.12.3 Beneficence and nonmaleficence

In many cases, one of the ethical problems highlighted when a study is conducted is the need to protect participants from any situations that may expose them to potential harm or discomfort. In this study, the participants mainly consisted of people over sixty years with diabetic foot ulcers who were attending the selected hospitals and health-care clinics for regular follow ups during the study period. This study involved a survey with an interviewer-administered questionnaire using a structured questionnaire; it did not involve any intervention in patient care. Therefore, there was no risk of physical or psychological harm in this study. The study was also considered to have low or minimal risk, as the researcher assured that she would not contribute to the participant's distress should the latter experience pain and discomfort during the interview. Should this happen, the researcher would end the interview and ensure that the nurse assigned to the participant was informed of the latter's pain status.

In this study, the participants were enrolled on a purely voluntary basis and were given the opportunity to ask any question at any time prior to, during, and after their participation. All participants were given the assurance prior to enrolling in the study that they could choose to terminate their participation in the study at any time without affecting their treatment. In addition, they were informed of the intended publication of the study results with a guarantee that their names and other personal information would not be disclosed.

3.12.4 Anonymity and confidentiality

To maintain anonymity, the researcher did not ask for or display the participants' personal information on the questionnaire (such as participant's name, hospital registration, or contact details). As proposed by Portney and Watkins (2009), the participants were identified by code. In this study, each participant was given a research number, for example, the first participant was coded as "001", for research purposes and data entry.

The completed paper questionnaires were kept in a locked filing cabinet, and a password-protected laptop was used in Malaysia to enter the data. The data were later transferred to a password-protected file server at Cardiff University for data protection and security.

Respect for the participants' privacy was guaranteed by conducting the interviews in a private room within the selected clinics. This was done to ensure the participants' privacy and confidentiality as well as to avoid disturbance. The researcher also kept the interview duration short to minimise the possibilities of the participants feeling burdened by the sessions.

3.13 Data storage

Back in Malaysia, the data obtained were entered into a password-protected device personally by the researcher, and the questionnaire papers were kept in a locked filing cabinet at the researcher's residence. These data and original questionnaires were accessible only to the researcher.

Upon the researcher's return to Cardiff, the data from the questionnaire were then electronically stored at Cardiff University's password-protected file server. The data generated from the study were accessible only to the researcher and her supervisors.

The data are to be kept for at least fifteen years, complying with the Guidelines of the Cardiff University for Confidentiality and Privacy (Data Protection Act 1998). This is to ensure that the confidentiality and the privacy of all participants are protected.

3.14 Data analysis

3.14.1 Quality checking of returned questionnaires

The first step of quality checking was the immediate manual check of the questionnaires to avoid problems, such as missing data and multiple answers of questions for which only one answer was needed, or irrelevant answers.

For completeness and accuracy, the two participants who filled in the questionnaire by themselves were asked to return their questionnaires personally to the researcher. The completed questionnaires were then checked immediately by the researcher.

As the study had been carried out through interviewer-administered questionnaires and rigorous checking of the questionnaires, there were no missing data in the study.

3.14.2 Encoding and entering data into computer

Each of the questionnaires was given an identification number upon the researcher receiving it. Subsequently, each question and answer was given a code number so that the data could be encoded and entered into the SPSS software. All the data were transformed into numeric coding in order to simplify the data analysis, such as “1” for male and “2” for female. Interval variables were entered as numbers.

The researcher then entered all the demographic data, clinical data, and health-care use, and the responses from the SF-MPQ, the SF-36, the DFS-SF, the Katz ADL, and the Lawton IADL instruments. Double entry was performed for data verification.

3.14.3 Checking for accuracy of data set

Before commencing the data analysis, it was vital to check the data for accuracy. Initial analysis outputs were conducted to check for missing and extreme values that were out of the range of normal possible values (Pallant 2013). The categorical data analysis was conducted using frequency tables, and the continuous data analysis was conducted using descriptive statistics. The initial analysis outputs of frequency and descriptive tests were checked to correct any errors before beginning the data analysis. At this point, some minor errors were noted and amended. Accordingly, the data were checked again using frequencies for categorical data and descriptive analysis for continuous data to confirm the accuracy of the data set.

3.14.4 Checking for data normality and outliers

In the analysis, the distributions of data were assessed for normality in order to decide the statistical methods to be used for inferential analysis. The following statistical tests were performed to establish the normal distribution of data: 1) histogram, 2) Skewness, 3) Kolmogorov-Smirnov, and 4) Shapiro-Wilk tests. Futher details are given in Section 4.3.1. The data did not show any outliers.

3.14.5 Statistical analysis to fulfil the research objectives

The IBM Statistical Package for Social Sciences (SPSS) version 21.0 (IBM Corp, Armonk, NY, USA) was used for the data analysis.

For the categorical data, where the values represent distinct categories, there may be no order between nominal categories or there may be a natural ordering of categories (ordinal) (Bland 2000). The participants' socio-demographic and clinical characteristics, their use of health care, and satisfaction, were measured using descriptive statistics, including frequency and percentages for categorical variables and means, standard deviations, medians, interquartile range and ranges for numerical variables.

The numerical data, where the values represent positions on a scale, may be of discrete values or values on a continuum, and so are limited by the precision of the measurement (Bland 2000). In this study, pain, health-related quality of life, and functional status, were measured using these validated scales (the SF-MPQ, SF-36, DFS-SF, Katz ADL, and Lawton IADL), and the scores on these instruments were interpreted as continuous measurements. These were summarised using descriptive statistics, where appropriate.

As already mentioned, the normality test, which was assessed using a histogram, the Skewness, the Kurtosis, the Kolmogorov-Smirnov and, the Shapiro-Wilk tests, indicated that the SF-MPQ was not normally distributed. As a result, a number of nonparametric statistical analyses were used for the inferential analysis (Pallant 2013). The statistical tests used are as follows:

- Spearman's Rank-Order Correlation to test the relationship between pain (SF-MPQ) and duration of diabetes mellitus, duration of foot ulcer episode,

health-related quality of life (SF-36 and DFS-SF), and functional status (Katz ADL and Lawton IADL).

- Kruskal-Wallis tests to examine the relationship between pain and number of co-morbidities, race, foot-ulcer episode, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution and type of dressing.

- The Man-Whitney U test was used to examine the relationship between pain and gender and the number of additional floors in the house.

- The Spearman's Rank-Order Correlation, the Kruskal-Wallis, and the Man-Whitney U tests were used to identify the similarities and differences between secondary care clinics and primary care clinics in terms of the pain experiences, health-related quality of life, functional status and use of the healthcare services. These tests were done separately for each population dataset. Then, a comparison was made between pain and the selected socio-demographic characteristics (age group, gender, race, religion, marital status, level of education, and number of additional floors in the house), the selected clinical characteristics (duration of diabetes mellitus, duration of foot ulcer episode, number of comorbidities, number of foot-ulcer episode, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution, type of dressing), as well as their health-related quality of life, functional status and use of the healthcare services.

For the Kruskal-Wallis tests, when the result obtained was seen to be statistically significant, the post hoc analysis was used in between the groups to identify which of the pairs within the groups contributed to the overall difference. A Bonferroni correction was used to avoid increasing type I errors due to repeated tests on the same data (Munro 2001). This involved dividing the desired level of significance by the number of paired comparison groups. For example, for a three-group comparison, there were three paired comparisons, and the Bonferroni corrected level of significance was α/number of comparisons, 0.05/3 =0.016. All statistical tests were two-tailed with $p < 0.05$ as the significance level.

Multiple linear regression was used to investigate the predictors of pain, which was treated as a continuous outcome. This approach assumes the dependent

variable is continuous and the independent predictor variables are either binary (coded 0 or 1) or continuous (Bland 2000).

Different types of data are summarised and analysed in different ways due to the properties of the different levels of measurement (Bland 2000). Table 3.3 summarises the variables, research questions, instruments, and statistical analysis adopted for the study.

The open-ended question in this study required the participants to provide their comments or suggestions in order to improve the quality of health services at the clinic. In this study, a content analysis method was used to analyse the answers from the open-ended questions. In content analysis, there is immersion in the text by the use of more structured analytical techniques; this involves four phases, as described by Hsieh and Shannon (2005). The phases included (1) sorting, (2) categorising, (3) naming themes, and (4) counting. Sorting responses involved entering responses into Microsoft Excel spread sheet as key words. The data were then transferred into SPSS software to categorise the responses. The responses were then entered under the headings of variables. For example, number 1 was allocated to the theme “staffing.” In this study, several themes were identified, for example, staffing, long waiting hours, follow-up, wound assessment, high treatment cost, and updating of information.

Table 3. 3 The summary of variables /research questions, instruments, and its statistical analysis

No	Variables /research questions	Instrument	Statistical test
1.	Socio-demographic characteristics	Socio- demographic characteristics data.	Descriptive statistic. Continuous data: Mean and standard deviation (SD). Category data: Number and percentage.
2.	Clinical characteristics	Clinical characteristics data.	Descriptive statistic. Continuous data: Mean, standard deviation (SD), median, interquartile range (IQR), range. Descriptive statistic. Category data: Number and percentage.
3.	- What are the pain experiences of people over sixty years with diabetic foot ulcers in Malaysia? - What are the similarities and differences in the pain experiences between people over sixty years in Clinic S and Clinic P?	The short form McGill pain questionnaire (SF- MPQ).	Descriptive statistic. Continuous data: median, interquartile range (IQR), Mean rank.
4.	- What is the health-related quality of life of people over sixty years with diabetic foot ulcers in Malaysia? - What are the similarities and differences in the health-related quality of life between people over sixty years in Clinic S and Clinic P?	- The medical outcomes study 36-item short-form health survey (SF-36). - Diabetic foot ulcer scale- short form (DFS-SF).	Descriptive statistic. Continuous data: Mean and standard deviation (SD).
5.	- What is the functional status of people over sixty years with diabetic foot ulcers in Malaysia? - What are the similarities and differences in the functional status between people over sixty years in Clinic S and Clinic P?	- Katz activities of daily living (Katz ADL). - Lawton instrumental activities of daily living (Lawton IADL).	Descriptive statistic. Continuous data: Mean and standard deviation (SD).

Table 3.3 The summary of variables /research questions, instruments, and its statistical analysis (Continued)

No	Variables /research questions	Instrument	Statistical test
6.	- What are the relationships between pain and the selected socio-demographic characteristic (age categories, gender, race, religion, marital status, level of education, and number of additional floors in the house), the selected clinical characteristic (duration of diabetes mellitus, number of co-morbidities, duration of foot ulcer episode, number of foot ulcer episode, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution, and type of dressing), the health-related quality of life, and the functional status of people over sixty years with diabetic foot ulcers in Malaysia? - What are the similarities and differences in relationship between the selected socio-demographic characteristics (age categories, gender, race, religion, marital status, level of education and number of additional floors), selected clinical characteristics (duration of diabetes mellitus, number of comorbidities, duration of foot ulcer episode, number of foot-ulcer episode, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution, type of dressing), the health-related quality of life and the functional status between people over sixty years in Clinic S and Clinic P?	- Socio- demographic characteristics data. - Clinical characteristics data. - Short form McGill pain questionnaire (SF- MPQ). - The medical outcomes study 36-item short-form health survey (SF-36). - Diabetic foot ulcer scale- short form (DFS-SF). - Katz activities of daily living (Katz ADL). - Lawton instrumental activities of daily living (Lawton IADL)	- Spearman's Rank-Order Correlation. - Man-Whitney U test. - Kruskal-Wallis tests and analysis using post-hoc Bonferroni test coefficient.

Table 3. 3 The summary of variables /research questions, instruments, and its statistical analysis (Continued)

No	Variables /research questions	Instrument	Statistical test
7.	What are the predictors of pain among Malaysian people over sixty years with diabetic foot ulcers?	- Socio- demographic characteristics data. - Clinical characteristics data. - Short form McGill pain questionnaire (SF-MPQ). - The medical outcomes study 36-item short-form health survey (SF-36). - Diabetic foot ulcer scale- short form (DFS-SF). - Katz activities of daily living (Katz ADL). - Lawton instrumental activities of daily living (Lawton IADL)	Multiple linear regression.
8.	- How do people over sixty years with diabetic foot ulcers use the health care clinic? - How do people over sixty years in Clinic S and Clinic P use the health care clinic?	Use the health care service data and responses of open-ended questions.	Descriptive statistic. Category data: Number and percentage.

Up to this point, this chapter has discussed the methods intended to be used in the study. The next section presents the details of the pilot study, which was carried out to ascertain whether the methods would work in practice.

3.15 The pilot study

The pilot study was conducted to test whether the procedures and logistics described previously would be suitable for the main study (see section 3.1 to section 3.14). A pilot study is a small-scale test that is run to improve the quality and effectiveness of the main study (Polit and Beck 2012). In the present study, the pilot study was performed to ensure that the procedures for the sample recruitment, information sheet, consent form, and data collection methods were appropriate for the main study. The test also served as a means to test the questionnaire in terms of its accuracy of translation, readability, and acceptability.

The methodology used for the pilot study was the same as the one used for the main study. The pilot study was conducted at the participating clinics. It involved the participants who met the inclusion criteria for the main study. Considerations from the pilot study are described in the following subsections.

3.15.1 Calculation of sample size for pilot study

A sample size calculation is required to estimate the sample size needed for a pilot study (Hertzog 2008). Hertzog (2008) suggested that a reasonable sample size for a pilot study is between twenty and forty participants; thus, a sample size of thirty participants was considered suitable for the pilot study of the present research.

A consecutive sample of thirty participants who met the inclusion and exclusion criteria was sought from the participating clinic prior to the commencement of the actual study. The characteristics of the pilot study participants are presented in Table 3.4. All thirty people were interviewed face-to-face by the researcher in order to complete the questionnaire. The participants were also asked to provide comments about the questionnaire and the survey process, for example, whether the questionnaire was clear and understandable. The pilot

study also served to identify any uneasiness that might be triggered during the interview session.

Table 3. 4 Characteristics of the pilot study participants (*n* = 30)

Variables	Range	Frequency	Percentage	Mean ± SD
Age (years)	60 –72			65.10±3.24
Gender				
Male		14	46.7	
Female		16	53.3	
Race				
Malay		15	50.0	
Chinese		10	33.3	
India		5	16.7	
Religion				
Muslim		15	50.0	
Buddhist		10	33.3	
Hindu		5	16.7	
Marital status				
Married		23	76.7	
Widowed		7	23.3	
Educational level				
Primary education		13	43.3	
Secondary education		15	50.0	
Tertiary education		2	6.7	
Number of floors				
Home with additional floors (1½ floors, 2 floors, 2 ½ floors and 3 floors and above)		14	46.6	
Home without additional floors (1 floor)		16	53.4	

3.15.2 Recruitment of sample

The participants were initially to be recruited from two secondary care and two primary care clinics. A few weeks later, the researcher was informed by the staff nurses that there were many people over sixty years with diabetic foot ulcers

who were referred to for follow-up or wound dressing at another nearby primary care clinic. It was decided that including another site would offer a higher possibility of getting more participants for the actual study. In order to ensure that this clinic would be a suitable location to recruit participants for the main study, a meeting with the Head of Department (HOD) and the clinic nurse manager of the potential primary care clinic was arranged by the researcher. The HOD and the clinic nurse manager were provided with all the information about the research, and the researcher was then granted permission to conduct the study there. Furthermore, the permission to conduct the study in this potential primary clinic was also granted by the director of the public health clinic. In addition, the researcher recruited three participants from the third primary care clinic and asked them to complete the questionnaire to see if they were suitable. The data of those recruited from the two secondary care and two primary care clinics were examined to see if those participants would be suitable for inclusion. There was no noticeable difference in the characteristics of participants from the two secondary care and two primary care clinics.

3.15.3 Adequacy of information provided to participants about the research

Throughout the study, it was found that none of the participants had any problem in understanding the content of the information sheet and the consent form. Few of the participants complained or felt that they needed further clarification about the study, though one participant raised a query about the Data Protection Act 1998. The researcher was able to explain to the participant of the procedures regarding data storage. Hence, no changes were required to the information sheet and the consent form provided for the participants.

3.15.4 Participants' understanding of the questions

The pilot study provided the researcher with the opportunity to identify any issues including participants' understanding of the questions and instructions given to them. Once their consent had been obtained, the participants were asked to complete the questionnaire in the presence of the researcher. The participants were encouraged to attempt all the questions.

The instruments used in this study for health-related quality of life consist of both generic (SF-36) and disease-specific (DFS-SF) instruments. A number of participants had difficulties differentiating between the SF-36 and the DFS-SF questionnaire because some of the questions were similar. In particular, they were confused and demonstrated some hesitation in answering the questions. The issues were resolved upon the researcher giving a clear explanation of the differences between the two sets.

3.15.5 Time required to complete the questionnaire

In general, the participants found that the time taken to complete the whole survey was acceptable. The whole process took about 45 minutes to 1 hour; 5 to 10 minutes were allocated for introduction and explanation of the study, 30 minutes to 1 hour were for answering the questionnaire, and another 5 to 10 minutes were to raise and discuss any problems that occurred while answering the questionnaire or the process of the study.

3.15.6 Effect of questionnaire on the participants

Another important part of the pilot study was to ensure that the participants were not distressed about completing the questionnaire. All the participants found the wordings acceptable, and none found any wordings to be offensive.

However, the pilot study revealed that the participants were anxious that they would miss their turn to see the doctors or their dressing slot while answering the questionnaire. Accordingly, the researcher decided to inform the staff nurse in charge during the interview session so that necessary actions could be taken to resolve the problem. The researcher also found this measure to be very helpful in the attempt to increase the response rate and facilitate the data collection process.

3.15.7 Validity and reliability of questionnaire

3.15.7.1 Content validity of Malay version of questionnaires

The validity of the contents of the DFS-SF, the Katz ADL, and the Lawton IADL was evaluated during the questionnaire development stage by experts in the field (see section 3.8). This was done to ensure that the questions outlined in the questionnaire were correct and were a comprehensive reflection of the concept of what was intended to be measured. However, the SF-MPQ and the SF-36 scales do not require content validity, as both have been widely used in Malaysia; therefore, it has already been accepted that they would have a satisfactory content validity.

3.15.7.2 Reliability of Malay version of questionnaires

A reliability test was also performed in the pilot study. Reliability refers to the extent of measurement for certain participants who are similar on applying this tool at different times (Bowling 2009). Zainuddin and Juliana (2012) stated that the reliability of a measure can be established by testing for both consistency and stability. For the reliability test, the Kuder–Richardson 20 (KR20) was used to establish the internal consistency reliability of the Katz ADL, as it is preferable for use with measures with dichotomous variables (e.g., 0 for dependence and 1 for independence) (Yaghmaei 2003). The Cronbach's alpha coefficient, on the other hand, is indicated for determining the internal consistency reliability of a measure with variables scored such as with Likert scales, for example, the DFS-SF and Lawton IADL scales. The internal reliability test illustrated that the Malay version of the DFS-SF had a total internal reliability of 0.87 as measured by Cronbach's alpha. The internal reliability tests for the Malay version of the Katz ADL and the Lawton IADL revealed Cronbach's alpha coefficients of 0.74 and 0.70 respectively. It was found that the Malay version of the questionnaire was compatible with the original English version.

Although other scales, including the SF-MPQ and the SF36, have already been validated in Malaysia, their internal consistency was re-assessed in this study. Portney and Watkins (2009) indicated that a Cronbach's alpha value of 0.50-0.70 was acceptable, while a value of 0.70 or greater shows good homogeneity

among the items (Pallant 2013). Table 3.4 presents the Cronbach's alpha coefficient of each scale, which is considered to be satisfactory. The researcher was unable to conduct the test–retest reliability, as the duration of the appointments for foot ulcer patients varied according to their needs.

Table 3. Reliabilities of the scales in the pilot study

Scales	Internal consistency (Kuder–Richardson 20 and Cronbach's alpha)
Diabetic foot ulcer scale short-form (DFS-SF).	0.87
Katz activity daily living (Katz ADL).	0.74
Lawton instrumental activities of daily living (Lawton IADL).	0.70
Short-form McGill pain questionnaire (SF-MPQ).	0.72
The medical outcomes study 36-item short-form health survey (SF-36).	0.73

3.15.8 Summary of the pilot study

The pilot study showed that recruiting people over sixty years with diabetic foot ulcers from the participating clinics was feasible. Initially, the participants were to be recruited from the two secondary care and two primary care clinics, but recruiting patients from another third primary care clinic was also found feasible.

The pilot study ascertained that no changes were required to the information sheet and the consent form provided for the participants. The length of time for completing the questionnaire was also acceptable to the participants. The study did not appear to cause any distress to the participants. The internal reliability tests for the Malay version of the Katz ADL and the Lawton IADL were compatible with the original English version.

All the data were imported into SPSS version 21.0 software to ascertain that the procedures would work for the full study.

Following the pilot study, minor modifications were made as follows:

- **Study location**

As stated previously, the original intention was to recruit participants from two secondary care and two primary care clinics. However, during the pilot study, the researcher found that many people over sixty years with diabetic foot ulcers

had been referred to a nearby primary care clinic for follow-up or wound dressing. Hence, the patients in the clinic were also deemed suitable for recruitment. Eventually, the main study was conducted in two secondary care and three primary care clinics.

- **Additional information about the study**

1. During the pilot test, socio-demographic and clinical data were also collected from the medical note reviews or the participants' self-reports. No information was found in the participants' medical records on the type of diabetic foot ulcers or on the physical examination. This query was removed following a discussion with the research supervisor.
2. The pilot study also allowed the researcher to gain experience in the administration of the questionnaire and other aspects of data collection.
3. During the pilot study, a few participants felt that they were in a position to discuss some issues not related to the study. While the researcher allowed this in the pilot study, a strategy was devised for the researcher to encourage the patients to speak to the appropriate clinic administrator, thereby maintaining the desired limitation of the clinician-researcher role.

3.16 Summary

This chapter reported on the methodology adopted for the study. The study design, questionnaire development, ethical considerations, pilot study, main study, and statistical analysis were discussed. A cross-sectional comparative study design was selected to explore the relationships between diabetic foot ulcer pain and the health-related quality of life and functional status of people over sixty years with diabetic foot ulcers in Malaysia. Appropriate instruments were selected and three instruments that were not available in Malay Language were translated. A pilot study on thirty consecutive people over sixty years with diabetic foot ulcers was conducted, and was found to be of great help in facilitating further study in terms of the appropriateness of the questionnaire and the feasibility of the data collection. In the main study, data were collected from three hundred people over sixty years with diabetic foot ulcers. All participants were ethically protected and informed about the focus of the study in detail. The statistical analysis methods were selected to analyse the data in fulfilling the research objectives. The next chapter will report the results of the full study.

CHAPTER 4

RESULTS

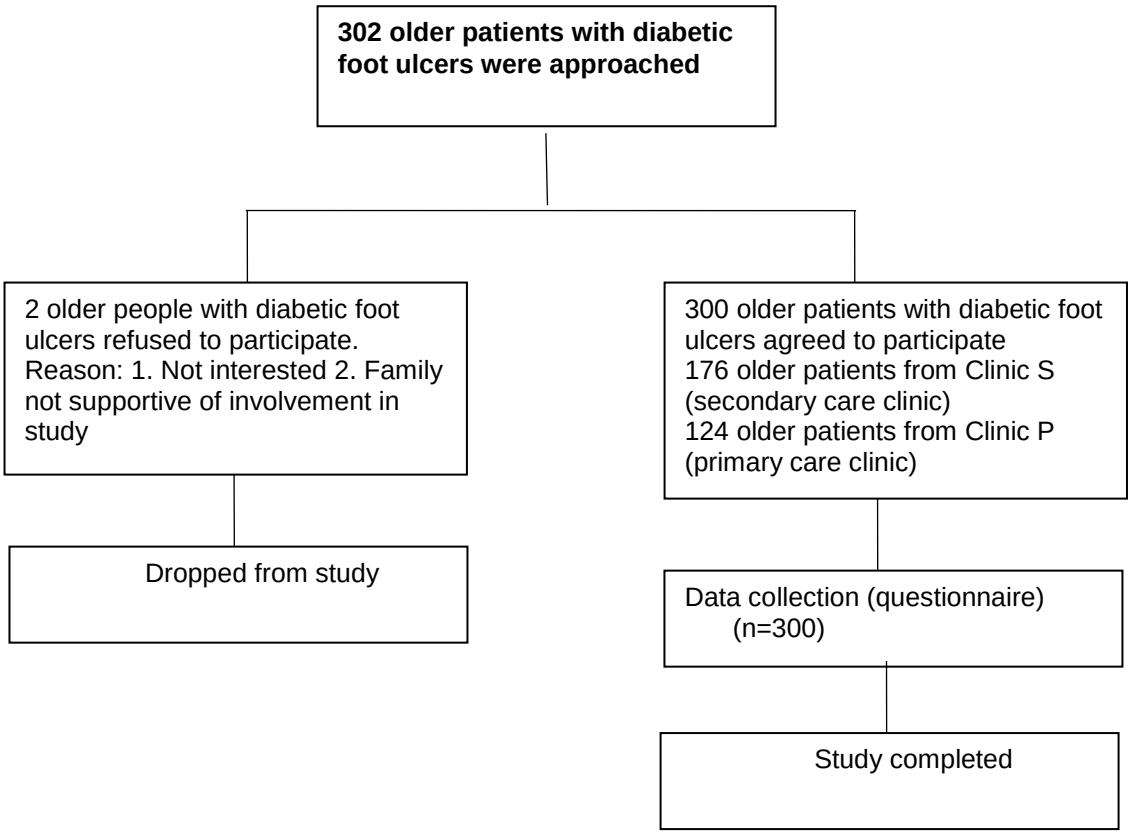
4.1 Introduction

This chapter is the first of two chapters that discuss the findings of the current study in relation to the research questions. The first section presents the descriptive results of the participants in terms of socio-demographic and clinical characteristics, and the SF-MPQ, SF-36, DFS-SF, Katz ADL and Lawton IADL. The descriptive analysis of frequency (n) and percentage (%) were used for categorical variables. Continuous variables, such as age, duration of diabetes mellitus, duration of foot ulcer episode, SF-MPQ, SF-36, DFS-SF, Katz ADL, and Lawton IADL, are presented with the mean, SD (standard deviation), range, median and interquartile range (IQR). The distribution of the SF-MPQ was non-normal; therefore, non-parametric inferential statistic tests were used to determine the relationship between the selected socio-demographic and clinical characteristics, the health-related quality of life, and the functional status. A stepwise multiple linear regression was conducted to investigate the predictors of pain.

4.2 Participants' recruitment

A total of 302 patients aged 60 years and above with diabetic foot ulcers were invited to participate in the study. Two of them, however, refused to take part. Hence, the total number of participants who gave consent and participated in the study was 300, as shown in Figure 4.1. Thus, the completion rate was 99%.

Figure 4. 1 Summary of the participant in the study



4.3 Testing underlying assumptions of normality and multiple linear regression

4.3.1 Assumptions for normality

Assessment of the data for normal distribution was undertaken using Skewness, Kurtosis, Kolmogorov-Smirnov, Shapiro-Wilk tests, and histogram,

4.3.1.1 Skewness, Kurtosis, Kolmogorov-Smirnov and Shapiro-Wilk tests

The Skewness value for each continuous variable was checked. Variables were considered normally distributed if the Skewness and Kurtosis value was between -1 and +1 (Pallant 2013). The findings of the Skewness and Kurtosis confirmed that the data on the SF-MPQ and Katz ADL were not normally distributed (Table 4.1).

A Kolmogorov-Smirnov (K-S) and Shapiro-Wilk (S-W) tests was used to test for normality on the continous variable. The K-S for SF-MPQ, degree of freedom (D) (300) = 0.193, $p < 0.05$ and the S-W for SF-MPQ, D (300) = 0.801, $p < 0.05$, the K-S for SF-36, D (300) = 0.193, $p > 0.05$ and the S-W for SF-36, D (300) = 0.984, $p > 0.05$, the K-S for DFS-SF, D (300) = 0.037, $p > 0.05$ and the S-W for DFS-SF, D (300) = 0.988, $p > 0.05$, the K-S for Katz ADL, D (300) = 0.487, $p < 0.05$ and the S-W for Katz ADL, D (300) = 0.427, $p < 0.05$, and the K-S for Lawton IADL, D (300) = 0.198, $p > 0.05$ and the S-W for Lawton IADL, D (300) = 0.883, $p > 0.05$. If the K-S and S-W are significant ($p < 0.05$), then the distribution is considered not normal (Pallant 2013). The findings of the K-S and S-W confirmed that the data on the SF-MPQ and Katz ADL were not normally distributed.

Table 4. 1 Confidence interval, skewness and kurtosis of the short-form McGill pain questionnaire, the medical outcomes study 36-item short-form health survey, diabetic foot ulcer scale – short- form, Katz activities of daily living, Lawton instrumental activities of daily living,

Variables	95% CI for mean	Skewness	Kurtosis
SF-MPQ	8.43 - 10.31	1.776	3.056
SF-36	51.46 - 54.45	0.257	-0.563
DFS-SF	51.14 - 54.35	0.227	-0.358
Katz ADL	5.52 - 5.74	-3. 088	9.646
Lawton IADL	6.46 - 6.74	-0.612	-0.312

Note: SF-MPQ= The short-form McGill pain questionnaire, Sf-36= The medical outcomes study 36-item short-form health survey (SF-36), DFS-SF= Diabetic foot ulcer scale – short- form, Katz ADL= Katz activities of daily living, Lawton IADL= Lawton instrumental activities of daily living, CI= confidence interval

4.3.1.2 Histogram

Normality plots in the form of histograms show the frequency of measurements and the shape of the data. Hence, the plots provide a visual judgment of whether the distribution approximates to a bell shape. That indicates the SF-MPQ, and Katz ADL, were not normally distributed. The graphical results for normality of SF-MPQ, SF-36, DFS-SF, Katz ADL, and Lawton are shown in Appendix 5 of A5.1 to A5.5.

Using of these measures of normal distribution it was concluded that the dependent variable (SF-MPQ) data were not normally distributed. Therefore, nonparametric statistical analyses were used for the inferential analysis (Pallant 2013).

4.3.2 Assumptions for multiple linear regression

In the current study a stepwise multiple linear regression analysis has been performed. In order to carry out this analysis certain assumption have to be met. The assumption of multiple regression were followed according to Pallant (2013):

4.3.2.1 Sample size

In order to preserve the generalisability of the results the sample size should have a certain sample size (Pallant 2013). Tabachnick and Fidell (2013) recommend the required sample size requirements, taking into account the

number of independent variables that you wish to use: N > 50 + 8m (where m = number of independent variables). If the sample size is too small, important effects may not come out as being statistically significant. The current study has 23 independent variables; therefore, N should be more than 234 cases (N>234). Therefore, with a sample size of 300 participants, the requirement for generalisability is met.

4.3.2.2 Multicollinearity

As suggested by Field (2009), multicollinearity was assessed by examining whether any of the tolerance values for the predictors were greater than 0.1. In the current study, midfoot, Grade 1 foot ulcer, gel dressing and daily dressing were excluded as not met the assumption of multicollinearity. The tolerance values for the others predictors from 0.31 to 0.79 (Table 4.2). As a result, there was no evidence of any strong linear relationship between predictors in the current study.

Table 4. 2 Tolerances of the predictors

Predictors	Tolerance
Female	0.72
More than 3 health problems	0.64
Duration of diabetes mellitus	0.68
3rd episode	0.79
Fore foot	0.61
Grade 3 foot ulcer	0.57
Grade 4 foot ulcer	0.68
Sterile water	0.70
Dermacyn	0.57
Antimicrobials	0.70
SF- 36 Role emotional	0.46
SF- 36 Vitality	0.40
SF- 36 Mental health	0.42
SF- 36 Social functioning	0.45
SF- 36 Bodily pain	0.47
DFS-SF Leisure	0.46
DFS-SF Physical health	0.36
DFS-SF Daily life	0.31
DFS-SF Negative emotion	0.38
DFS-SF Worried about ulcer	0.54
DFS-SF Bothered by ulcer care	0.43
Katz ADL	0.53
Lawton IADL	0.59

4.3.2.3 Outliers

Multiple regression is very sensitive to outliers, which are either very high or very low scores (Pallant 2013). Outliers are known to distort statistics. In order to find the presence of outliers the residual scatterplot will be assessed. Any cases with standardized residuals that exceed -3.3 or 3.3 are defined as outliers (Tabachnick and Fidell 2013). For the current study no case was found to exceed either -3.3 or 3.3. Therefore it can be concluded that no outliers are present within these data.

4.3.2.4 Normality, linearity and homoscedasticity

Normality of residuals was checked by using histogram of residuals. As the histogram does appear a bell shaped curve, it is assumed that there are no major deviations from normality (Pallant 2013) (see Appendix 5 of A5.6).

Linearity and homoscedasticity is checked by assessing the Residual Scatterplot. The overall shape of the scatterplot is importance when checking for normality, linearity and homoscedasticity (Tabbachnick and Fidell 2013). As the scatterplot roughly has a rectangular shape and most scores are concentrated around the centre, it can be concluded that the data is not non-linear or heteroscedastic. As all variables were found to be normally distributed, homoscedasticity could already be assumed (see Appendix 5 of A5.7).

In conclusion, the assumptions of multiple regression appeared to be satisfied.

4.4 Socio-demographic characteristics of the participants.

For the current study, the socio-demographic characteristics of the participants, comprising age, gender, race, religion, marital status, educational level, and the number of floors of the houses they occupied were explained accordingly.

4.4.1 Age and gender

The age of the participants ranged from 60 to 88 years old. The mean age was 65.19 ± 4.98 years. More than 80% of the participants (n= 247, 82.3%) were in the 60 to 69 years old age group, followed by the 70 to 79 years old age group (n= 48, 21.7%). Only five participants (1.7%) were aged 80 years old and above.

The majority of participants were male (n= 164, 54.7%) and 45.3% (n= 136) were female. Table 4.3 shows the age and gender of the participants.

Table 4. 3 Age and gender

Variables	Range	Frequency	Percentage	Mean ± SD
Age (years)	60 – 88			65.19 ± 4.98
Age categories				
60 to 69		247	82.3	
70 to 79		48	16.0	
80 and above		5	1.7	
Total		**300**	**100**	
Gender				
Male		164	54.7	
Female		136	45.3	
Total		**300**	**100**	

4.4.2 Race and religion

Nearly half of the participants were Malays (n= 141, 47%), followed by Indians and others (n= 85, 28.3%) and Chinese (n= 74, 24.7%). The majority of the participants were Muslim (n= 141, 47%), followed by Hindu and Buddhist (n= 73, 24.3%) respectively. Only 13 (4.4%) of the participants were Christians and others. Table 4.4 presents the race and religion of the participants.

Table 4. 4 Race and religion

Variables	Frequency	Percentage
Race		
Malay	141	47.0
India + Other	85	28.3
Chinese	74	24.7
Total	**300**	**100.0**
Religion		
Muslim	141	47.0
Buddhist	73	24.3
Hindu	73	24.3
Christian + Other	13	4.4
Total	**300**	**100.0**

4.4.3 Marital status

Table 4.5 shows the marital status of the participants. Over half of the participants (n= 217, 72.3%) were married, 70 (23.4%) were widowed, divorced or separated. The remaining 13 (4.3%) were still single.

Table 4. 5 Marital status

Variables	Frequency	Percentage
Marital status		
Married	217	72.3
Widowed + Divorced + Separated	70	23.4
Single	13	4.3
Total	**300**	**100.0**

4.4.4 Educational level

Table 4.6 illustrates the distribution of the educational level of the participants in the current study. It is apparent from the table that the majority of the participants (n= 286, 95.3%) had attended school, while only a minority had never been to school (n= 14, 4.7%). Of those who had attended school, most had completed secondary education (n= 157, 52.3%), primary education (n= 104, 34.7%), or tertiary education (n= 25, 8.3%).

Table 4. 6 Educational level

Variables	Frequency	Percentage
Educational level		
Secondary education	157	52.3
Primary education	104	34.7
Tertiary education	25	8.3
Never	14	4.7
Total	**300**	**100.0**

4.4.5 Number of floors in the house

In order to study the relationship between pain and additional floors, the number of floors in the participants' homes was observed. This category was divided into home without additional floors, and homes with additional floors (1½ floors, 2 floors, 2 ½ floors and 3 floors and above), as illustrated in Table 4.7. Nearly 60% of participants (n=179, 59.7%) reported having additional floors in their home, while 40.3% (n=121) reported having no additional floors.

Table 4. 7 Number of floors

Variables	Frequency	Percentage
Number of floors		
Home with additional floors (1½ floors, 2 floors, 2 ½ floors and 3 floors and above)	179	59.7
Home without additional floors (1 floor)	121	40.3
Total	**300**	**100.0**

4.5 Clinical characteristic of the participants

For the current study, the clinical characteristics of the participants, which were set out as their duration of diabetes, types of diabetes treatment, number of foot ulcer episode, duration of foot ulcer episode, site of foot ulcer, the cause of diabetic foot ulcer, frequency of dressing change, type of cleaning solution, type of dressing, treatment related instruction or method, history of related operations, severity of wound ulcer (Wagner wound classification (1981)) and pain relief use, were explained accordingly.

4.5.1 Duration of having diabetes mellitus

Participants were asked to state the duration of their diabetes mellitus. As illustrated in Table 4.8, the duration of diabetes mellitus ranged from 0.25 to 35 years with a median duration of 18.5 years (IQR= 15).

Table 4. 8 Duration of diabetes mellitus in years

Variables	Median (IQR)	Range	Mean	± SD
Duration of diabetes mellitus in years	18.5 (15)	0.25 - 35	17.53	8.58

Note IQR: Interquartile range

4.5.2 Number of other co-morbidities besides diabetes present at the time of the study

Table 4.9 shows other health problems associated with the participants at the time of the study. 132 (44.0%) participants reported that they had one additional health problem apart from diabetes, followed by 29.7% (n= 89) of participants who reported having two additional health problems, and 8% (n= 24) of participants who reported having more than three health problems. Meanwhile, 18.3% (n= 55) of participants reported they had no other health problems except diabetes. Some of the participants identified the type of their health problem, for example, renal problem, hypertension, or heart disease. However, other participants only gave the number of health problems.

Table 4. 9 Number of other co-morbidities besides diabetes

Variables	Frequency	Percentage
Number of other co- morbidities besides diabetes, present at the time of the study		
1	132	44.0
2	89	29.7
0	55	18.3
>3	24	8.0
Total	**300**	**100.0**

4.5.3 Types of diabetes treatment

On the treatment for diabetes, the majority of the participants were on insulin therapy (n= 149, 49.7%), while another 80 (26.7%) were on oral hypoglycaemia agents. 44 participants (14.7%) were on both insulin and oral hypoglycaemia agents while only 27 (9%) participants were on diet control alone. Table 4.10 shows the types of diabetes treatment received by the participants.

Table 4. 10 Types of diabetes treatment

Variables	Frequency	Percentage
Types of diabetes treatment		
Insulin therapy	149	49.7
Oral hypoglycaemia agents	80	26.7
Both insulin and oral hypoglycaemia agents	44	14.7
Diet control only	27	9.0
Total	**300**	**100.0**

4.5.4 Foot ulcer episode

Data regarding foot ulcer episodes is presented in Table 4.11. More than half of the participants (n= 172, 57.3%) were experiencing their first episode of foot ulcer. For more than 30% of the participants (n= 98, 32.7%), it was the second episode of foot ulcer. Meanwhile, a total of 19 (6.3%) and 11 (3.7%) of the participants were experiencing a third episode and more than three episodes of foot ulcer respectively.

Table 4. 11 Foot ulcer episode

Variables	Frequency	Percentage
Foot ulcer episode		
1st episode	172	57.3
2nd episode	98	32.7
3rd episode	19	6.3
More than three episodes	11	3.7
Total	**300**	**100.0**

4.5.5 Duration of foot ulcer episode

Participants were asked to state the duration of their foot ulcer. As illustrated in Table 4.12, the foot ulcer duration ranged from 1 to 96 months with a median duration of 3 months (IQR= 8).

Table 4. 12 Duration of foot ulcer episode in months

Variables	Median (IQR)	Range	Mean	± SD
Duration of foot ulcer episode months	3 (8)	1 - 96	8.04	12.73

Note IQR: Interquartile range

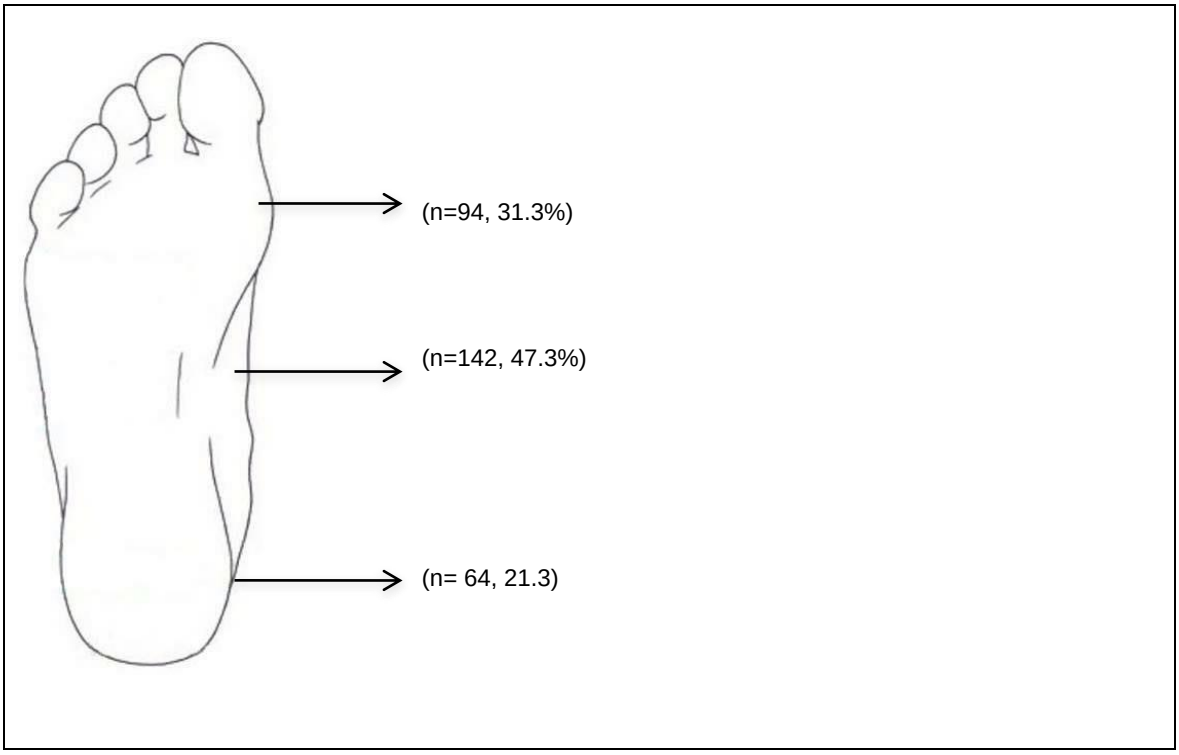
4.5.6 Site of foot ulcer

Regarding the site of foot ulcers, most were at the midfoot (n= 142, 47.3%), ninety-four (31.3%) were at the forefoot, and sixty-four (21.3%) were located at the hindfoot. Table 4.13 and Figure 4.2 show the site of foot ulcer formation.

Table 4. 13 Site of foot ulcer

Variables	Frequency	Percentage
Site of foot ulcer		
Midfoot	142	47.3
Forefoot	94	31.3
Hindfoot	64	21.3
Total	**300**	**100.0**

Figure 4. 2 Site of foot ulcer



4.5.7 Severity of foot ulcer

The severity of the diabetic foot ulcers was classified using the Wagner wound classification system (Wagner 1981) and indicated a range of grades from grade 1 to grade 4. The most common stages of ulcers were grade 2 (n= 118, 39.3%), grade 1 (n= 112, 37.3%), grade 3 (n= 59, 19.7%), and grade 4 (n= 11, 3.7%). Table 4.14 identifies the Wagner wound classification of the participants.

Table 4. 14 Wagner wound classification

Variables	Frequency	Percentage
Wagner wound classification		
Grade 1	112	37.3
Grade 2	118	39.3
Grade 3	59	19.7
Grade 4	11	3.7
Total	**300**	**100.0**

4.5.8 The perceived cause of diabetic foot ulcers

The perceived causes of the diabetic foot ulcers identified by the participants are summarised in Table 4.15. The majority of the participants perceived that the main cause of their foot ulcer was injury (n= 183, 61%), followed by spontaneous blister (n= 48, 16%), no evidence of cause (n= 44, 14.7%), improperly fitting footwear (n= 20, 6.7%), burns (n= 4, 1.3%), and fungal infection (n= 1, 0.3%).

Table 4. 15 The perceived cause of foot ulcer

Variables	Frequency	Percentage
The perceived cause of foot ulcer		
Injury	183	61.0
Spontaneous blister	48	16.0
No evidence of cause	44	14.7
Improperly fitting foot wear	20	6.7
Burns	4	1.3
Fungal infection	1	0.3
Total	**300**	**100.0**

4.5.9 Frequency of dressing change

The frequency of dressing change varied, but the most extensive was reported to be on a daily basis (n= 120, 40%), 32.7% (n= 98) of the participants had their dressing changed when needed, 14% (n= 42) had their dressing changed once a week, and 13.3% (n= 40) had their dressing changed on alternate days. Most participants in the study reported they had changed the dressing by themselves. The common reason given for this was that the dressing had got wet when they had a bath. Table 4.16 presents the frequency of dressing change among the participants in the study.

Table 4. 16 Frequency of dressing change

Variables	Frequency	Percentage
Frequency of dressing change		
Daily	120	40.7
When needed	98	32.7
Once a week	42	14.0
Every alternate day	40	13.3
Total	**300**	**100.0**

4.5.10 Type of cleaning solution

Regarding the type of cleaning solution, the most common cleaning solution used was saline (n= 101, 33.7%). Following that, more than 20% (n= 64, 21.3) used Dermacyn, 61 (20.3) used Hydrocyn, 59 (9.7%) used Prontosan, and 15 (n= 5%) used sterile water. Table 4.17 shows the type of cleaning solution used.

Table 4. 17 Type of cleaning solution

Variables	Frequency	Percentage
Type of cleaning solution		
Saline	101	33.7
Dermacyn	64	21.3
Hydrocyn	61	20.3
Prontosan	59	19.7
Sterile water	15	5.0
Total	**300**	**100.0**

4.5.11 Type of dressing

The type of dressing participants used is shown in Table 4.18. The majority (n= 234, 78%) of the participants used gel dressing as their dressing type. More than 10% (n=36, 12%) used dry gauze, 5% (n= 15) used foam, 3.3% (n= 10) used antimicrobials, and 1.7% (n= 5) used wet saline soaked dressing. Examples of gel dressing include Intrasite gel and duoderm gel, and an example of antimicrobial dressings is silver dressing.

Table 4. 18 Type of dressing

Variables	Frequency	Percentage
Type of dressing		
Gel dressing	234	78.0
Dry gauze	36	12.0
Foam	15	5.0
Antimicrobials	10	3.3
Wet Saline soaked dressing	5	1.7
Total	**300**	**100.0**

4.5.12 Self-management strategies

The participants were asked about which was the most important self-management strategy to reduce pressure on their foot ulcer (see Table 4.19). The most frequently strategy was resting the foot, which accounted for 32.3% (n= 97) of the participants. This was followed by restriction of mobility level, which was used by 22% (n= 66) of the participants, diabetic sandal (n= 62, 20.7%), elevation of limb (n= 50, 16.7%), non-weight bearing walking with crutches (n= 11, 3.7%), the use of back slap and of insoles (n= 4, 1.3% each), orthosis (n= 3, 1%), wheelchair (n= 2, 0.7%), and total contact cast (n= 1, 0.3%).

Table 4. 19 Most important self-management strategies mentioned by each patient

Variables	Frequency	Percentage
Self-management strategies		
Foot rest	97	32.3
Restriction of mobility level	66	22.0
Diabetic sandal	62	20.7
Elevation of limb	50	16.7
Non – weight bearing walking crutches	11	3.7
Insole	4	1.3
Back slab	4	1.3
Total contact cast	1	0.3
Orthosis	3	1.0
Wheelchair	2	0.7
Total	**300**	**100.0**

4.5.13 Surgical intervention/procedures

In regard to surgical intervention or procedures related to foot ulcers, nearly half of the participants (n= 122, 40.7%) had undergone debridement, followed by ray amputation (n= 28, 9.3%), below knee amputation (n= 14, 4.7%), toe amputation (n=12, 4%), forefoot amputation (n= 7, 2.3%), skin graft (n= 5, 1.7%) and above-knee amputation (n= 3, 1%). Meanwhile, slightly more than one third of the participants (n= 109, 36.3%) had not undergone any surgical intervention or procedure. The distribution of surgical intervention/procedures related to foot ulcers is shown in Table 4.20.

Table 4. 20 Surgical intervention/procedures

Variables	Frequency	Percentage
Surgical intervention/procedures		
Debridement	122	40.7
None	109	36.3
Ray amputation	28	9.3
Below knee amputation	14	4.7
Toe amputation	12	4.0
Forefoot amputation	7	2.3
Skin graft	5	1.7
Above knee amputation	3	1.0
Total	**300**	**100.0**

4.5.14 Pain relief use

Participants were asked whether they took pain relief for the pain they experienced (see Table 19). Most participants 158 (52.7%) reported not taking any pain relief. A total of 142 (47.3%) participants who had taken pain relief reported that they perceived it to be effective in relieving their pain. The pain relief use of the participants in the study is presented in Table 4.21.

Table 4. 21 Pain relief use

Variables	Frequency	Percentage
Do you take pain relief for your pain?		
No	158	52.7
Yes	142	47.3
Total	**300**	**100.0**
Does medication relieve your pain?		
Yes	142	47.3

4.6 Pain experiences

The first research question was “What are the pain experiences by people over sixty years with diabetic foot ulcers in Malaysia?” To understand this issue, participants’ pain experiences were measured using the SF-MPQ. Participants were asked to rate if the pain that they had experienced in the previous one week was consistent with the quality of each word and, if it was present, to rate it as mild, moderate, or severe. The rank value of each participant’s response was added to give the sum of the rank values for the participant. Then, the total scores for all participants were added to give the sum for the pain rating index (PRI) for the group. Three pain scores were derived from the sum of the PRI of the rank values of the chosen words; 1) sensory (first 11 descriptors), 2) affective (following 4 descriptors) and 3) PRI total (all descriptors).

The second part of the SF-MPQ consisted of 100 mm long horizontal VAS scores with end points of “no pain” to “worst pain imaginable”. Participants were asked to rate their pain on the scale to indicate their pain experience.

The last part of the SF-MPQ consisted of an PPI score measured on a 6-point verbal rating scale (VRS) (“no pain” to “excruciating pain”), which was given a

numeric value (0 – 5). Participants were asked to choose one of six words to describe their pain experience.

To address this research question, frequency, percentage, median, IQR, range, mean, and SD were performed.

4.6.1 Descriptive analysis of the short-form McGill pain questionnaire scores

When participants were asked to rate their pain experience, the median total PRI for the participants in the study was 6 (IQR= 8, range = 1 to 41). Participants more commonly endorsed the sensory descriptors of pain quality than they did the affective descriptors with median (IQR) PRI values of 5 (7) and 1 (3) respectively. The descriptive data derived from the SF-MPQ are show in Table 4.22.

Table 4. 22 The short-form McGill pain questionnaire scores

Variables	Median (IQR)	Possible range	Range	Mean	± SD
PRI - Total	6 (8)	0 - 45	1 - 41	9.37	8.28
PRI - Sensory	5 (7)	0 - 33	0 - 33	7.46	6.47
PRI - Affective	1(3)	0 - 12	0 -12	1.92	2.61

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range
PRI – Total = Pain Rating Index Total; PRI – Sensory = Pain Rating Index Sensory; Affective PRI= Pain Rating Index

4.6.2 Verbal descriptor chosen to describe the quality of pain in the short-form McGill pain questionnaire

Rank ordered descriptor use frequencies for the participants are presented in Table 4.23. The sensory words most commonly to describe diabetic foot ulcer-related pain were throbbing (n= 225, 75%), shooting (n= 213, 71%), aching (n= 205), stabbing (n= 154, 51.3%) and cramping (n= 138, n= 46%). The affective descriptors most commonly used to describe diabetic foot ulcer-related pain were tiring exhausting (n= 126, 42%) and fearful (n= 100, 33.3%)

Table 4. 23 Rank ordered descriptor use frequencies of the short-form McGill pain questionnaire in people over sixty years with diabetic foot ulcer

Variables	Frequency	Percentage
Sensory		
Throbbing	225	75
Shooting	213	71
Aching	205	68.3
Stabbing	154	51.3
Cramping	138	46
Tender	107	35.6
Heavy	96	32
Sharp	94	31.3
Hot-burning	54	18
Gnawing	53	17.6
Splitting	46	15.3
Affective		
Tiring exhausting	126	42
Fearful	100	33.3
Punishing cruel	81	27
Sickening	65	21.6

4.6.3 Visual analogue scale

The intensity of pain is assessed by VAS (100 mm) in the second part of the SF-MPQ. There was a 100 mm line; at the left end was written 'no pain' and at the right end was written 'worst possible pain'. The participants were asked to mark with an "X" on the line to indicate their pain at that time. The results showed that the pain experienced ranged from 0 to 92.7 mm with a median of 35.4 (IQR= 29.17) (Table 4.24).

Table 4. 24 The Visual analogue scale

Variables	Median (IQR)	Possible range	Range	Mean	± SD
VAS - pain intensity	35.4 (29.17)	0 -100 mm	0 – 92.7 mm	39.04	19.94

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range
VAS = Visual Analogue Scale

4.6.4 Present pain index

Table 4.25 shows the PPI, which is in the third part of the SF-MPQ; this describes the pain that the participants were feeling at the time of answering the questionnaire. There were 0 descriptors of pain listed in the form ranging from no pain to excruciating. Most participants rated their evaluative overall diabetic foot ulcer pain as mild (n= 129, 43%), followed by discomforting (n= 104, 34.7%), distressing (n= 43, 14.3%), no pain (n= 14, 4.7), and finally horrible (n= 10, 3.3%).

Table 4. 25 Descriptor of present pain index

Variables	Frequency	Percentage
Mild	129	43.0
Discomforting	104	34.7
Distressing	43	14.3
No pain	14	4.7
Horrible	10	3.3
Total	**300**	**100.0**

4.7 Health-related quality of life

The second research question was “What is the health-related quality of life of people over sixty years with diabetic foot ulcers in Malaysia?” Participants were assessed using the SF-36 and DFS-SF in order to understand their generic and disease-specific health-related quality of life respectively. To address this research question, median, IQR, range, mean, and SD were calculated.

4.7.1 Health-related quality of life measured using the medical outcomes study 36 item short- form helath survey

The SF-36 was used in the current study to measure generic health-related quality of life. Table 4.26 displays the SF-36 scores for the participants in the study. The physical health component of the SF-36 subscales includes physical functioning, role physical, bodily pain and general health. The mental health component includes vitality, social functioning, role emotional and mental health subscales.

Using the SF-36 version 2, the mean of the physical health summary score was lower (mean = 45.98, SD = 14.24, range 15 to 85) than the mean mental health summary score (mean = 60.06, SD = 14.02, range 28 to 90). However, each domain in the SF-36 was scored higher than the norm of 50 except physical functioning (mean = 33.8, SD = 22.43, range = 5 to 100), physical role (mean = 49.7, SD = 20.73, range 12.5 to 100) and general health (mean = 42.58, SD = 12.73, range 10 to 90). In summary, the survey indicates that the participants had poor health-related quality of life in the physical functioning, physical role, and general health domains.

Table 4. 26 The Medical outcomes study 36- item short- form health survey scores

Variables SF-36	Median (IQR)	Possible range	Range	Mean	± SD
SF-36 Physical health summary	**44.38**	**0-100**	**15-85**	**45.98**	**14.24**
Physical functioning	30 (35)	0-100	5-100	33.88	22.43
Physical role	50 (32.5)	0-100	12.5-100	49.77	20.73
Bodily pain	55 (22.5)	0-100	10-100	57.68	20.61
General health	40 (10)	0-100	10-90	42.58	12.73
SF-36 Mental health summary	**60.06**	**0-100**	**28-90**	**59.94**	**14.02**
Vitality	50 (15)	0-100	10-90	51.25	13.76
Social functioning	50 (25)	0-100	12.5-100	58. 46	20.93
Emotional role	75 (50)	0-100	16.6-100	66.77	25.58
Mental health	64 (20)	0-100	24-88	63.26	13.91
Total SF-36	**51 (18)**	**0-100**	**23.5- 86**	**52.96**	**13.13**

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range

4.7.2 Health-related quality of life measured using the diabetic foot ulcer scale short- form

The DFS-SF was used in the current study to measure disease - specific health-related quality of life. The DFS-SF scores were transformed so that they were from 0-100. On this scale, 0 is the lowest score, while 100 is the highest score. The highest score for the participants in the study was the negative emotions subscale (mean = 73.73, SD = 25.30) followed by the bothered by ulcer care (mean =69.60, SD = 23.33), physical health (mean= 55.01, SD = 20.58), dependence/ daily life (mean= 53.30, SD = 25.76), and leisure (mean= 42.86, SD = 29.17), while the lowest was the worried about ulcers/feet (mean= 28.15, SD = 21.63). Table 4.27 gives the summary of the DFS-SF score for the participants of the current study

Table 4. 27 Diabetic foot ulcer scale short –form scores

Variables DFS-SF	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**
Leisure	50 (45)	0-100	0-100	42.86	29.17
Physical health	55 (25)	0-100	0-100	55.01	20.58
Dependence/ daily life	55 (35)	0-100	0-100	53.30	25.76
Negative emotions	75 (41.6)	0-100	0-100	73.73	25.30
Worried about ulcers/feet	28.84 (37.5)	0-100	0-61.54	28.15	21.63
Bothered by ulcer care	75 (43.7)	0-100	0-100	69.60	23.33
Total DFS-SF	**52 (18.8)**	**0-100**	**21.60-92.8**	**52.74**	**14.14**

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range

4.8 Functional status

The third research question was “What is the functional status of people over sixty years with diabetic foot ulcers in Malaysia?” Participants were assessed using the Katz ADL and Lawton IADL in order to understand their functional status. To address this research question, the median, IQR, range, mean and SD were calculated.

4.8.1 Functional status measured using the Katz activity of daily living

The Katz ADL was used to measure the functional status of participants with diabetic foot ulcers. The possible scores range from 0 to 6, with lower scores indicating functional impairments, and a score of 6 indicating full functioning. The participants in the current study had scores ranging from 0 to 6 (median = 6; IQR = 0). The majority of participants had scores 6/6, indicating independence in activities of daily living. Table 4.28 shows the Katz ADL scores for the participants in the study.

Table 4. 28 The Katz activity of daily living scores

Variables	Median (IQR)	Possible range	Range	Mean	± SD
Katz activity of daily living	6 (0)	0 - 6	0 - 6	5.63	1.05

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range

4.8.2 Functional status measured using Lawton instrumental activities of daily living

Table 4.29 presents the Lawton IADL used in the current study. The Lawton IADL consisted of an 8-item measure, with the possible scores ranging from 0 (low function) to 8 (high function). In the current study, the participants had a median score of 7 (IQR= 2) with scores ranging from 3 to 8. Most scores were at 7/8 or 8/8, very close to the maximum score of 8/8, indicating participants' independence in instrumental activities of daily living.

Table 4. 29 Lawton instrumental activities of daily living scores

Variables	Median (IQR)	Possible range	Range	Mean	± SD
Lawton instrumental activities of daily living	7 (2)	0 - 8	3 - 8	6.60	1.24

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range

4.9 Associations between pain and selected socio-demographic characteristic, selected clinical characteristic health-related quality of life and functional status.

The fourth research question was “What are the relationships between pain and selected socio-demographic characteristics (gender, age categories, race, religion, marital status, level of education, and number of floors in the house), selected clinical characteristics (duration of diabetes mellitus, co-morbidities, duration of foot ulcer episode, number of foot ulcer episode, site of foot ulcer, frequency of dressing change, type of cleaning solution, type of dressing, and Wagner wound classification), health-related quality of life, and functional status of people over sixty years with diabetic foot ulcers in Malaysia?” This association was determined using the Mann-Whitney U, Kruskal-Wallis test and Spearman’s rank correlation coefficient.

4.9.1 Association between pain and socio-demographic characteristic.

4.9.1.1 Association between pain and gender

The association between pain and gender was investigated. As there was a non-normal distribution, the Mann-Whitney U test was used to examine the association. There was a significant difference in the SF-MPQ score and gender ($z= -3.72$, $p < 0.001$).

Thus, based on the median value score, the female participants obtained the highest median value on the SF-MPQ score compared to the male participants. This indicated that pain was worse in the female participants than in the males. These results are provided in Table 4.30.

Table 4. 30 Associations between the short-form McGill pain questionnaire score and gender

Variables	SF-MPQ score			z	p-value
	Median	IQR	Mean rank		
Gender				-3.72	<0.001*
Male	5.00	6.00	133.59		
Female	8.00	11.00	170.90		

Note: z= Mann-Whitney U test; IQR: Interquartile range

4.9.1.2 Association between pain and number of floor within the house

To determine whether there was difference in the SF-MPQ score in those participants with homes with additional floors and homes without additional floors, the Mann-Whitney U test (due to the non-normal distribution) was used. There was no significant difference in scores for participants with homes with additional floors and homes without additional floors in relation to pain (z= -0.76, p= 0.447) (Table 4.31).

Table 4. 31 Association between the short-form McGill pain questionnaire score by number of floors

Variables	SF-MPQ score			z	p-value
	Median	IQR	Mean rank		
Number of floors				-0.76	0.447
Home with additional floors (1½ floors, 2 floors, 2 ½ floors and 3 floors and above)	6.00	7.00	147.25		
Home without additional floors (1 floor)	6.00	10.00	154.93		

Note: z= Mann-Whitney U test; IQR: Interquartile range

4.9.1.3 Association between pain and age categories

The Kruskal–Wallis test was used to examine the association between the SF-MPQ score and age categories. Participants were divided into three groups according to their age (Group 1: 60-69 years, Group 2: 70 -79 years, Group 3: 80 and above). The association between these variables did not reach statistical significance (X^2= 2.08, p= 0.353) (Table 4.32).

Table 4. 32 Association between the short-form McGill pain questionnaire score by age categories

Variables	SF-MPQ score			Kruskal-Wallis X^2	p-value
	Median	IQR	Mean rank		
Age categories (in years)				2.08	0.353
60 to 69	6.00	9.00	153.56		
70 to 79	6.00	7.50	138.47		
80 and above	5.00	5.50	114.90		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.1.4 Association between pain and race

Regarding race, participants were divided into three groups according to their race (Group 1: Malay, Group 2: Chinese, Group 3: Indian + other). The Kruskal–Wallis test in Table 4.33 suggests that there was no statistically significant difference in the SF-MPQ score for the three groups (X^2= 2.33, p= 0.312).

Table 4. 33 Association between the short-form McGill pain questionnaire score and race

Variables	SF-MPQ score			Kruskal-Wallis X^2	p-value
	Median	IQR	Mean rank		
Race				2.33	0.312
Malay	8.00	10.00	154.49		
Chinese	6.00	5.00	137.20		
India+ other	6.00	8.00	155.46		

Note: Other was grouped with India in light of the small numbers of participants; X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.1.5 Association between pain and religion

The association between the SF-MPQ score and religion was examined by the Kruskal-Wallis test. Participants were divided into four groups according to their religion (Group 1: Muslim, Group 2: Buddhist, Group 3: Hindu; Group 4: Christian + other).

There was no statistically significant difference in the SF-MPQ score for the four groups (X^2= 2.71, p= 0.438) (Table 4.34).

Table 4. 34 Association between the short-form McGill pain questionnaire score and religion

Variables	SF-MPQ score			Kruskal-Wallis X^2	p-value
	Median	IQR	Mean rank		
Religion				2.71	0.438
Muslims	7.00	10.00	154.25		
Buddhist	6.00	5.00	136.17		
Hindu	6.00	8.00	155.86		
Christian + other	6.00	13.00	160.23		

Note: Other was grouped with Christians in light of the small numbers of participants; X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.1.6 Association between pain and marital status

The association between pain and marital status was examined using non-parametric testing with the Kruskal-Wallis test because the data were not distributed normally. Participants were divided into three groups according to their marital status (Group 1: married, Group 2: widowed+ divorced+ separated, Group 3: single) (Table 4.35).

There was a statistically significant difference in the SF-MPQ score for the three groups (X^2= 7.13, p= 0.028). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction revealed the significant difference in the SF-MPQ score between married and single (z= -2.63, p= 0.009), but not between widowed + divorced + separated and married (z= -0.92, p= 0.356) and widowed + divorced + separated and single (z= -1.92, p= 0.55).

Based on the median value scores, the result showed that the participants who were married had higher median scores on the SF-MPQ. This indicated that participants who were married experienced more pain than did single participants.

Table 4. 35 Association between the short-form McGill pain questionnaire score and marital status

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Marital Status				7.13	0.028*
Married	7.00	10.00	155.87		
Widowed+ divorced+ separated	6.00	7.50	144.74		
Single	4.00	3.00	91.81		

Note: Divorced and separated were grouped with widowed in light of the small numbers of participants; X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.1.7 Associations between pain and educational level

Table 4.36 presents the association between the SF-MPQ score and educational level. The Kruskal–Wallis test (due to the non-normal distribution) was used. Participants were divided into four groups according to their educational level (Group 1: secondary education, Group 2: primary education, Group 3: tertiary education, Group 4: never).

There was no statistically significant difference in the SF-MPQ score for the four groups (X^2= 2.93, p= 0.402). However, based on median scores for all groups, it was observed that never participants had higher SF-MPQ scores, followed by primary and secondary. Participants with tertiary education had the lowest SF-MPQ scores. This indicated that as the educational level decreased, the scores for the SF-MPQ increased.

Table 4. 36 Association between the short-form McGill pain questionnaire score and educational level

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Educational Level				2.93	0.402
Secondary education	6.00	9.50	150.58		
Primary education	7.00	7.75	155.11		
Tertiary education	4.00	6.00	123.96		
Never	7.50	15.00	162.82		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.2 Association between pain and clinical variables

4.9.2.1 Association between pain and duration of having diabetes mellitus

The association between pain and duration of having diabetes mellitus was examined using non parametric testing with Spearman's rank correlation coefficient because of the non-normal distribution; the statistical analysis of the data obtained did not indicate a significant correlation between the SF-MPQ score and duration of diabetes mellitus (Spearman's rank correlation coefficient (p)= -0.10, p= 0.083). This result suggests that duration of diabetes mellitus does not have an effect on pain (Table 4.37).

Table 4. 37 Association between the short-form McGill pain questionnaire score and duration of diabetes mellitus

Variables	Spearman's rank correlation coefficient	p-value
Duration of diabetes mellitus	-0.10	0.083

4.9.2.2 Association between pain and duration of foot ulcer episode

The association between pain and duration of foot ulcer episode was examined using non parametric testing with Spearman's rank correlation coefficient because of the non-normal distribution; the statistical analysis of the data obtained did not indicate a significant correlation between the SF-MPQ score and duration of foot ulcer episode (Spearman's rank correlation coefficient (p)= 0.09, p= 0.127). This result suggests that duration of foot ulcer episode does not have an effect on pain (Table 4.38).

Table 4. 38 Association between the short-form McGill pain questionnaire score and duration of foot ulcer episode

Variables	Spearman's rank correlation coefficient	p-value
Duration of foot ulcer episode	0.09	0.127

4.9.2.3 Association between pain and co-morbid conditions

The association between the SF-MPQ score and co-morbidities was examined. The Kruskal-Wallis test (due to non-normal distribution) was used. Participants were divided into four groups according to their number of health problems (Group 1: 1, Group 2: 2, Group 3: 0, Group 4: > 3).

There was a statistically significant difference in the SF-MPQ score for the four groups (X^2= 10.61, p=0.014). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction revealed the significant difference in the SF-MPQ score between one health problem and more than three health problems (z= - 3.065, p= 0.002) and, no health problem and more than three health problems (z= - 2.868, p= 0.004).

Based on the median value scores, the participants who had more than three health problems besides diabetes obtained the highest median value on the SF-MPQ score compared to the participants who had one and no health problems. Therefore, pain in participants who had more than three health problems was more severe than in the participants who had one and no health problems (Table 4.39).

Table 4. 39 Association between the short-form McGill pain questionnaire score and number of other co-morbidities

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Number of other co-morbidities				10.61	0.014*
1	6.00	7.00	143.22		
2	7.00	8.50	152.49		
0	6.00	6.00	141.57		
>3	13.5	14.75	203.58		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.2.4 Association between pain and foot ulcer episode

To determine whether the number of foot ulcer episodes in participants affected the SF-MPQ score, the Kruskal–Wallis test was used (for non-normal distribution). Participants were divided into four groups according to the number of foot ulcer episodes (Group 1: 1st episode, Group 2: 2nd episode, Group 3: 3rd episode, Group 4: more than 3 episodes).

There was a statistically significant difference in the SF-MPQ score for the four groups (X^2= 8.55, p= 0.036). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction were used to identify significant differences between pairs of groups. There was a significant difference in the SF-MPQ score between participants undergoing the 1st episode of foot ulcer and those undergoing the 3rd episode of foot ulcer (z= -2.81, p= 0.005) and 2nd episode of foot ulcer, and 3rd episode of foot ulcer (z= -2.25, p= 0.019).

Based on the median value scores, the participants who were undergoing a 3rd episode of foot ulcer obtained the highest median value on the SF-MPQ score compared to those undergoing the 1st episode and 2nd episodes of foot ulcer. This indicated that participants who were undergoing a 3rd episode of foot ulcer experienced more pain compared to those undergoing their 1st episode and 2nd episode of foot ulcer (Table 4.40).

Table 4. 40 Association between the short-form McGill pain questionnaire score and number of foot ulcer episodes

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Foot ulcer episode				8.55	0.036*
1st episode	6.00	7.00	143.17		
2nd episode	7.00	10.00	151.22		
3rd episode	10.00	18.00	202.18		
More than 3 episodes	9.00	12.00	169.36		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.2.5 Association between pain and site of foot ulcer

Table 4.41 presents the association between the SF-MPQ score and the site of the foot ulcer. The Kruskal-Wallis test (due to non-normal distribution) was used. Participants were divided into three groups according to the site of their foot ulcer (Group 1: midfoot, Group 2: forefoot, Group 3: hindfoot).

There was a statistically significant difference in the SF-MPQ score for the three groups (X^2= 9.23, p= 0.010). The Mann-Whitney U test and post-hoc Bonferroni correction were also used in the post hoc analysis to identify any significant differences between pairs of groups. The result revealed that there was a significant difference in the SF-MPQ score between midfoot and forefoot (z= -2.93, p= 0.003) and forefoot and hindfoot (z= -2.15, p= 0.031), but not between midfoot and forefoot (z= -2.1, p= 0.830).

Based on the median value scores, the participants who had an ulcer at the forefoot obtained the highest median value on the SF-MPQ score compared to those with an ulcer at the midfoot and hindfoot, indicating pain was worse in participants who had a foot ulcer at the forefoot than at the midfoot and hindfoot.

Table 4. 41 Association between the short-form McGill pain questionnaire score and site of foot ulcer

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Site of foot ulcer				9.23	0.010*
Midfoot	6.00	6.00	139.34		
Forefoot	8.00	13.5	172.90		
Hindfoot	6.00	8.50	142.36		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.2.6 Association between pain and severity of foot ulcer.

The association between the SF-MPQ scores and the severity of the foot ulcer were examined. The Kruskal-Wallis test (due to non-normal distribution) was used. Participants were divided into four groups according to their wound classification (Group 1: Grade 2, Group 2: Grade 1, Group 3: Grade 3, Group 4: Grade 4).

There was statistically significant difference in the SF-MPQ score for the four groups (X^2 = 37.12, p= <0.001). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction revealed the significant difference in the SF-MPQ score between Grade 1 and Grade 2 (z= -2.58, p= 0.010), Grade 1 and Grade 3 (z= -5.47, p= <0.001), Grade 1 and Grade 4 (z= -3.37, p= 0.001), Grade 2 and Grade 3 (-3.21, p= 0.001), Grade 2 and Grade 4 (z= -2.89, p= 0.004), and Grade 3 and Grade 4 (z= -1.98, p= 0.048).

Based on the median value scores, the participants who had Grade 4 foot ulcer obtained the highest median value on the SF-MPQ score compared to those with Grade1, Grade 2 and Grade 3, indicating pain was worse in participants who had Grade 4 foot ulcer than Grade1, Grade 2 and Grade 3 (Table 4.42).

Table 4. 42 Association between the short-form McGill pain questionnaire score and severity of foot ulcer

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Wagner wound classification				37.12	<0.001*
Grade 1	5.00	3.75	120.61		
Grade 2	7.00	7.25	149.85		
Grade 3	11.00	13.00	194.25		
Grade 4	37.00	34.00	227.18		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.2.7 Association between pain and frequency of dressing change

The association between the SF-MPQ score and the frequency of dressing change was analysed. As there was a non-normal distribution, the Kruskal-Wallis test was used. Participants were divided into four groups according to the frequency of their dressing change (Group 1: daily, Group 2: when needed, Group 3: once a week, Group 4: every alternate day).

There was no statistically significant difference at the p <0.05 levels in the SF-MPQ score for the four groups (X^2 = 4.88, p= 0.181). This result suggests that frequency of dressing does not have an effect on pain (Table 4.43).

Table 4. 43 Association between the short-form McGill pain questionnaires core and frequency of dressing

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Frequency of dressing				4.88	0.181
Daily	7.00	10.00	160.18		
When Needed	6.00	7.00	143.89		
Once a week	5.00	7.25	129.87		
Every alternate day	7.50	8.50	159.34		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.2.8 Association between pain and type of cleaning solution

As the distribution was non-normal, the Kruskal-Wallis test was used to determine the pain and how this was affected by type of cleaning solution. Participants were divided into five groups according to their type of cleaning solution (Group 1: Saline, Group 2: Dermacyn, Group 3: Hydrocyn, Group 4: Prontosan, Group 5: sterile water).

There was a statistically significant difference in the SF-MPQ score for the five groups (X^2= 22.36, p <0.001). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction were used in the post hoc analysis to identify any significant differences between pairs of groups. There was a significant difference in the SF-MPQ score between saline and sterile water (z= -3.79, p <0.001), Dermacyn and sterile water (z= -4.04, p <0.001), Hydrocyn and sterile water (-3.84, p <0.001), and Prontosan and sterile water (z= -2.81, p= 0.005).

Based on the median value scores, the participants who used sterile water as a cleaning solution obtained the highest median value on the SF-MPQ score compared to the participants who used saline, Dermacyn, Hydrocyn, and Prontosan. Therefore, the participants who used sterile water as a cleaning solution experienced more severe pain than did the participants who used saline, Dermacyn, Hydrocyn, and Prontosan (Table 4.44).

Table 4. 44 Relationship between the short-form McGill pain questionnaire score and type of cleaning solution

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Type of cleaning solution				22.36	<0.001*
Saline	6.00	8.00	144.91		
Dermacyn	5.00	8.00	126.91		
Hydrocyn	6.00	6.00	146.59		
Prontosan	8.00	10.00	167.97		
Sterile water	17.00	24.00	235.97		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

4.9.2.9 Association between pain and type of type of dressing

To determine whether the type of dressing affected the SF-MPQ score, due to the non-normal distribution the Kruskal-Wallis test was used. Participants were divided into five groups according to their type of dressing (Group 1: gel dressing, Group 2: dry gauze, Group 3: foam, Group 4: antimicrobials, Group 5: wet saline soaked dressing).

There was a statistically significant difference in the SF-MPQ score for the five groups (X^2= 20.06, p<0.001). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction revealed the significant difference in the short-form McGill pain questionnaire scores between gel dressing and antimicrobials (z= -4.16, p<0.001), dry gauze and antimicrobials (z= -3.38, p= 0.001), and between foam and antimicrobials (z= -2.48, p= 0.013).

Based on the median value scores, the participants who used antimicrobials for their dressing obtained the highest median value on the SF-MPQ score compared to those who used gel dressing, dry gauze, and foam. In summary, participants who used antimicrobials for their dressing experienced more pain compared to those participants who used gel dressing, dry gauze, and foam (Table 4.45).

Table 4. 45 Association between the the short-form McGill pain questionnaire score and type of dressing

Variables	**SF-MPQ score**			**Kruskal-Wallis X^2**	**p-value**
	Median	**IQR**	**Mean rank**		
Type of dressing				20.06	<0.001*
Gel dressing	6.00	7.00	143.74		
Dry gauze	6.00	10.00	147.40		
Foam	9.00	9.00	174.43		
Antimicrobials	25.00	20.00	259.35		
Wet saline soaked dressing	14.00	21.50	199.50		

Note: IQR: Inter quartile range

4.9.3 Association between pain and health-related quality of life

4.9.3.1 Association between pain and generic health-related quality of life

To determine whether there is any significant relationship between pain and generic health-related quality of life, the associations between the SF-MPQ score and SF-36 scales including physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health were examined by the Spearman's rank correlation coefficient.

As a result, seven SF-36 subscales were reported as having significant small-to-medium negative correlations with the SF-MPQ score; these subscales were role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health (Spearman's rank correlation coefficient (p) range from -0.11 to -0.40, p values 0.012 to < 0.001) (Table 4.46). Thus, participants who experienced more pain had a reduced health-related quality of life in role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health.

Table 4. 46 Spearman's rank correlation coefficient between the short-form McGill pain questionnaire score and medical outcomes study 36-item short- form health survey scores

Variables	Spearman's rank correlation coefficient p	p-value
Physical functioning	-0.11	0.063
Physical role	-0.14	0.014*
Bodily pain	-0.40	<0.001*
General health	-0.15	<0.001*
Vitality	-0.34	<0.001*
Social functioning	-0.34	<0.001*
Emotional role	-0.37	<0.001*
Mental health	-0.40	<0.001*

Note: * Indicated statistically significant result.

4.9.3.2 Association between pain and disease specific health-related quality of life

To determine the relationship between diabetic foot ulcer pain and disease specific health-related quality of life, the Spearman's rank correlation coefficient was used to estimate the correlation between the SF-MPQ and the DFS-SF subscales.

However, all the subscales of DFS-SF had significant small-to-medium negative correlations with the SF-MPQ score (Spearman's rank correlation coefficient (p) range from -0.24 to -0.46, all $p < 0.001$) (Table 4.47). Therefore, participants who experienced more pain had a worse health-related quality of life in leisure, physical health, daily life, negative emotion, worried about ulcer and bothered by ulcer.

Table 4. 47 Spearman's rank correlation coefficient between the short-form McGill pain questionnaire and diabetic foot ulcer scale short –form subscales

Variables	Spearman's rank correlation coefficient p	p-value
Leisure	-0.25	<0.001*
Physical health	-0.46	<0.001*
Daily life	-0.24	<0.001*
Negative emotion	-0.42	<0.001*
Worried about ulcer	-0.29	<0.001*
Bothered by ulcer	-0.46	<0.001*

Note: DFS-SF: Diabetic foot ulcer scale- short –form; * Indicated statistically significant result.

4.9.4 Association between pain and functional status

4.8.4.1 Association between pain and Katz activity of daily living

To identify whether there was a significant relationship between pain and activities of daily living, the associations between the SF-MPQ score and the Katz ADL were examined by the Spearman's rank correlation coefficient; moderate negative correlations were demonstrated (Spearman's rank correlation coefficient (p)= -0.35 p< 0.001). In summary, participants who experienced more pain had a worse functional status (Table 4.48).

Table 4. 48 Spearman's rank correlation coefficient between the short-form McGill pain questionnaire score and the Katz activity of daily living

Variables	Spearman's rank correlation coefficient p	p-value
Katz activity of daily living	-0.35	<0.001*

4.9.4.2 Association between pain and Lawton instrumental activity daily living

To determine whether there was a significant relationship between pain and activities of daily living, the correlation was evaluated by the Spearman's rank correlation coefficient (Table 4.49). However a mild negative correlation was reported (Spearman's rank correlation coefficient (p)= -0.21 p< 0.001). Thus, participants experienced more pain and had reduced instrumental daily living.

Table 4. 49 Spearman's rank correlation coefficient between the short-form McGill pain questionnaire score and Lawton instrumental activity daily living

Variables	Spearman's rank correlation coefficient p	p-value
Lawton instrumental activity daily living	-0.21	<0.001*

4.10 Predictors of pain

The fifth research question was “What are the predictors of pain among Malaysian people over sixty years with diabetic foot ulcers?” A stepwise multiple linear regression was used to explore the predictors of pain among Malaysian people over sixty years with diabetic foot ulcers. It is presented in two sub-sections. The first sub-section presents the results of the simple linear regression tests. The second sub-section presents the results of the multiple linear regression which explores the predictors of pain.

4.10.1 Simple linear regression

In total, 61 variables (including dummy variables) were then fitted as the independent variable in a simple linear regression model with pain as the dependent variable. The categories were as follows: age (60-69, 70-79, 80 and above), gender (male, female), race (Malay, non-Malay), religion (Muslim, non-Muslim), marital status (single, married, widowed + divorced + separated), level of education (never, primary, secondary, tertiary), number of additional floors, duration of diabetes, duration of foot ulcer episode, number of other co-morbidities (0, 1, 2, more than 3); number of foot ulcer episodes (1st episode, 2nd episode, 3rd episode, more than 3 episodes), site of foot ulcer (forefoot, midfoot, hindfoot), type of cleaning solution (saline, sterile water, Prontosan, Hydrocyn, Dermacyn), type of dressing (dry gauze, saline soaked, antimicrobials, gel dressing, foam), frequency of dressing change (daily, every alternate day, once a week, when needed), Wagner wound classification (Grade 1, Grade 2, Grade 3, Grade 4), SF-36 physical functioning, SF-36 role physical, SF-36 role emotional, SF-36 vitality, SF-36 mental health, SF-36 social functioning, SF-36 bodily pain, SF-36 general health, DFS-SF- leisure, DFS-SF- physical health, DFS-SF- daily life, DFS-SF- negative emotion, DFS-SF- worried about ulcer, DFS-SF- bothered by ulcer, Katz ADL, and Lawton IADL

In a simple linear regression, 27 variables appeared to be significant predictors of pain ($p< 0.05$). These were gender, number of other co-morbidities: more than 3, duration of diabetes mellitus, 3rd episode of foot ulcer, forefoot, midfoot, sterile water, dermacyn, antimicrobials, gel dressing, daily dressing, Grade 1,

Grade 3, Grade 4, SF-36 role emotional, SF-36 vitality, SF-36 mental health, SF-36 social functioning, SF-36 bodily pain, DFS-SF- leisure, DFS-SF- physical health, DFS-SF- daily life, DFS-SF- negative emotion, DFS-SF- worried about ulcer, DFS-SF- bothered by ulcer, Katz ADL, and Lawton IADL.

4.10.2 Multiple linear regression

Table 4.50 presents the multiple regression analysis that was constructed using the stepwise method to answer research question 5. An initial investigation was conducted to ensure the non-violation of the regression assumptions of multicollinearity, normality, linearity, and homoscedasticity.

Overall, 27 variables were included in the multiple linear regression. These were gender, number of other co-morbidities: more than 3, duration of diabetes mellitus, 3rd episode of foot ulcer, forefoot, midfoot, sterile water, dermacyn, antimicrobials, gel dressing, daily dressing, Grade 1, Grade 3, Grade 4, SF-36 role emotional, SF-36 vitality, SF-36 mental health, SF-36 social functioning, SF-36 bodily pain, DFS-SF- leisure, DFS-SF- physical health, DFS-SF- daily life, DFS-SF- negative emotion, DFS-SF- worried about ulcer, DFS-SF- bothered by ulcer, Katz ADL, and Lawton IADL. However, midfoot, Grade 1 foot ulcer, gel dressing and daily dressing were excluded as not met the assumption of multicollinearity

The results show that the model could significantly explain 52% of the variation in the SF-MPQ score (R^2 = 0.52 % (Table 4.50). Six variables were significantly associated with pain [gender (b = -1.59, p = 0.025), sterile water (b = 6.24, p<0.001), antimicrobials (b = 7.15, p = 0.001), Grade 4 (b = 12.73, p< 0.001), SF-36 bodily pain (b = -0.06, p = 0.009) and DFS-SF- bothered by ulcer care (b = -0.09, p< 0.001)].

In summary, there were six predictors of pain in the current study. First, the male participants had a lower pain score than the female participants. Second, the participants who had a Grade 4 foot ulcer experienced more pain than participants with other grades of foot ulcer. Third, the participants who used sterile water as a cleaning solution experienced more pain than the participants who used other cleansing solutions. Fourth, the participants who used antimicrobial dressings experienced more pain compared with those

participants who used dry gauze, saline soaked, foam, or gel dressings. Fifth, the participants who experienced bodily pain had a higher pain score. Finally, the participants who claimed they were bothered by ulcer care were those who had a higher pain score.

Table 4. 50 Adjusted association of variables with the short-form McGill pain questionnaire score using simple linear regression and multiple linear regression

Variables	SLR[a]				MLR[b]				
	B[c]	95% CI		p-value	Adj. B[d]	95% CI		t-stat.	p-value
		Lower	Upper			Lower	Upper		
Duration of diabetes mellitus	-0.14	-0.25	-0.03	0.013*					
Duration of foot ulcer episode	0.009	-0.08	0.07	0.809					
Gender	-3.62	-5.46	-1.77	<0.001*	-1.59	-2.99	-0.20	-2.26	0.025
Race	0.53	-1.35	2.42	0.578					
Religion	0.80	-1.09	2.69	0.404					
Number of floors in house	1.64	-0.27	3.55	0.09					
Age categories									
60-69	1.83	-0.63	4.29	0.144					
70-79	-1.52	-4.08	1.05	0.246					
80 & above	-3.84	-11.19	3.51	0.305					
Marital status									
Single	-4.49	-9.09	0.11	0.056					
Married	1.07	-0.79	3.41	0.223					
Widowed + divorced + separated	-0.42	-2.65	1.81	0.713					
Number of comorbidities									
0	-0.66	-3.09	1.77	0.593					
1	-1.15	-3.04	0.75	0.235					
2	-0.33	-2.39	1.74	0.755					
>3	6.11	2.71	9.52	<0.001*					
Foot ulcer episode									
1st episode	-1.58	-3.48	0.32	0.103					
2nd episode	-0.18	-2.19	1.83	0.86					
3rd episode	6.23	2.42	10.03	0.001*					
More than 3 episodes	1.59	-3.42	6.60	0.533					
Site of foot ulcer									
Forefoot	4.12	2.14	6.09	<0.001*					
Midfoot	-3.04	-4.89	-1.18	0.001*					
Hindfoot	-0.76	-3.06	1.54	0.518					

a. Simple linear regression.
b. Multiple linear regressions (R^2= 0.52): The model reasonably fits well: Model assumptions are met.
c. Crude regression coefficient.
d. Adjusted regression coefficient.

Table 4.50 Adjusted association of variables with the short-form McGill pain questionnaire score using simple linear regression and multiple linear regression (Continued)

Variables	SLR[a]				MLR[b]				
	B[c]	95% CI		p-value	Adj. B[d]	95% CI		t-stat.	p-value
		Lower	Upper			Lower	Upper		
Type of cleaning solution									
Saline	-1.02	-3.00	0.98	0.316					
Sterile water	10.48	6.32	14.64	<0.001*	6.24	3.01	9.47	3.80	<0.001
Protosan	2.36	0.002	4.72	0.050					
Hydrocyn	-1.21	-3.55	1.13	0.308					
Dermaycyn	-2.66	-4.95	-0.38	0.022*					
Type of dressing	0.36	-2.54	3.26	0.807					
Dry gauze									
Saline soaked	6.13	-1.21	13.46	0.101					
Antimicrobials	16.06	11.14	20.98	<0.001*	7.15	3.14	11.16	3.51	0.001
Gel dressing	-4.65	-6.86	-2.43	<0.001*					
Foam	2.97	-1.34	7.28	0.176					
Frequency of dressing									
Daily	2.34	0.44	4.25	0.016*					
Every alternate day	-0.18	-2.95	2.59	0.901					
Once a week	-2.15	-4.86	0.55	0.118					
When needed	-1.29	-3.29	0.72	0.208					
Severity of foot ulcer									
Grade 1	-4.82	-6.69	-2.95	<0.001*					
Grade 2	-0.66	-2.59	1.27	0.499					
Grade 3	4.43	2.108	6.74	<0.001*					
Grade 4	16.59	11.95	21.24	<0.001*	12.73	8.97	16.49	6.67	<0.001

a. Simple linear regression.
b. Multiple linear regressions (R^2= 0.52): The model reasonably fits well: Model assumptions are met.
c. Crude regression coefficient.
d. Adjusted regression coefficient.

Table 4.50 Adjusted association of variables with the short-form McGill pain questionnaire score using simple linear regression and multiple linear regression (Continued)

Variables	SLR[a]				MLR[b]				
	B[c]	95% CI		p-value	Adj. B[d]	95% CI		t-stat.	p-value
		Lower	Upper			Lower	Upper		
SF-36									
Role physical	-0.04	0.09	-0.005	0.081					
Role emotional	-0.11	-0.15	-0.08	<0.001*					
Vitality	-0.16	-0.23	-0.09	<0.001*					
Mental health	-0.23	-2.94	-0.17	<0.001*					
Social functioning	-0.12	-0.16	-0.07	<0.001*					
Bodily pain	-0.16	-0.20	-0.12	<0.001*	-0.06	-0.09	-0.14	-2.63	0.009
General health	-0.06	-0.13	0.02	0.121					
DFS-SF									
Leisure	-0.04	-0.08	-0.01	0.008*					
Physical health	-0.18	-0.22	-0.14	<0.001*					
Daily life	-0.05	-0.09	-0.02	0.003*					
Negative emotion	-0.12	-0.15	-0.08	<0.001*					
Worried about ulcer	-0.08	-0.13	-0.04	<0.001*					
Bothered by ulcer care	-0.16	-0.19	-0.12	<0.001*	-0.09	-0.12	-0.06	-6.02	<0.001
Katz ADL	-2.96	-3.84	-2.08	<0.001*					
Lawton IADL	-0.16	-2.36	-0.89	<0.001*					

a. Simple linear regression.
b. Multiple linear regressions (R^2= 0.52): The model reasonably fits well: Model assumptions are met.
c. Crude regression coefficient.
d. Adjusted regression coefficient.

This section addresses the sixth research question which is to explore how the people over sixty years with diabetic foot ulcers use the clinic.

4.11 The use of clinics among people over sixty years with diabetic foot ulcers in Malaysia

The sixth research question was “How do people over sixty years with diabetic foot ulcers use the clinics in Malaysia? To address this research question, frequency and percentage calculations were performed while content analysis was used to analyse the answers to the open-ended question.

4.11.1 Information about pain control

Participants were asked to indicate how much information about wound pain control they had received. Regarding receiving verbal information, 46.3% (n= 139) of participants reported that they had not received any information on how to manage their pain, 23% (n= 69) of participants had received some information, 18.3% (n= 55) of participants had received a little information, while 12.3% (n= 37) of participants had received a lot of information.

Regarding receiving written information, a similar result was found. Over half 58.3% (n= 139) of participants reported that they had not received written information on how to manage their pain; 17.7% (n= 53) of participants had received some information, and 16.3% (n= 49) of participants had received a little information, while 7.7% (n= 23) of participants had received a lot of information. Table 4.51 shows how much information the participants received about wound pain control.

Table 4. 51 Received information about wound pain control

Variables	Frequency	Percentage
How much verbal information about wound pain control have you received?		
None	139	46.3
Some	69	23.0
A little	55	18.3
A lot	37	12.3
Total	**300**	**100.0**
How much written information about wound pain control have you received?		
None	175	58.3
Some	53	17.7
A little	49	16.3
A lot	23	7.7
Total	**300**	**100.0**

4.11.2 Provision of wound pain control

When participants were asked who gave them the greatest amount of information about wound pain control, most commonly reported were the nurse (n= 106, 35.3%) and the doctor (n= 38, 12.7 %) followed by family or friends (n= 14, 4.7%), the internet and magazines (n= 3, 1% each), and other health care person (n= 1, 0.3%). However, 45% (n= 135) of participants reported that no one had provided them with information. Table 4.52 shows the provision of wound pain control.

Table 4. 52 Provision of wound pain

Variables	Frequency	Percentage
Who have you received information from about wound pain control?		
No one	135	45.0
Nurse	106	35.3
Doctor	38	12.7
Family / friends	14	4.7
Internet	3	1.0
Magazine	3	1.0
Other health care person	1	0.3
Total	**300**	**100.0**

4.11.3 Satisfaction with wound care

Table 4.53 indicates how satisfied the participants were with the care of their wound they had received: 91% (273) of participants stated that they were very satisfied or satisfied with the care they had received regarding their wound, with only 0.7% (n= 2) expressing dissatisfaction, while 8.3% (25) of participants stated they were somewhat satisfied with the care they had received regarding their wound.

Table 4. 53 Satisfaction with wound care

Variables	Frequency	Percentage
How satisfied have you been so far with the care of your wound has received in the health care clinic?		
Satisfied	247	82.3
Very satisfied	26	8.7
Somewhat satisfied	25	8.3
Dissatisfied	2	0.7
Total	**300**	**100.0**

4.11.4 Comments and suggestion by Malaysian people over sixty years with diabetic foot ulcers to improve the quality of health services at the clinic

The open-ended question asked participants to provide information regarding their comments or suggestions to improve the quality of health services at the clinic.

As mentioned previously in Chapter 3, the open-ended question was analysed using content analysis. For the current study, the steps of analysing the written answers to the open questions that the research followed could be summarised as sorting the responses, categorizing, naming themes, and counting.

Overall, 260 comments did not address any specific theme but gave general positive feedback to the clinic: “good services”, “everything was excellent”, “nothing to complain about” and “no suggestions”.

As shown in Table 4.54, seven themes that emerged from the analysis were staffing, the long waiting hours, follow-ups, the attitude of healthcare

professionals, the poor wound assessment, the availability of up-to-date information, and the high cost of treatment.

Table 4. 54 Themes describing comments and suggestion by Malaysian people over sixty years with diabetic foot ulcers to improve the quality of health services at the clinic

Themes	Data example
Staffing (n=20)	More doctors and nurses who are specialist in wound care. Now, there are many female nurses. This clinic needs more male nurses.
The attitude of healthcare professionals (n=9)	The nurses are great; they are very helpful. The nurses are very good and polite, and the doctors are OK. Doctors and nurses do not understand the patient's condition. They do not take me seriously and listen to my complaints. They want to finish their task quickly.
The long waiting hours (n=6)	The most painful thing is that we come early, but having arrived early, we need to wait. Sometimes it will take many hours. Everyone was complaining about the long waiting hours in this clinic.
The poor wound assessment (n=2)	Should perform wound assessment before the dressing. I think the nurses did a poor assessment, and I was in great pain during and after the dressing.
Follow-up (n=1)	Once a week is too long; I mostly prefer to change my dressing two times a week.
The high cost of treatment (n=1)	The Dermaycn was very expensive.
The availability of up-to-date information (n=1)	Please update the latest information about clinic activity and the telephone number on the website.

From Table 4.55, it can be seen that staffing (n=20, 87%) was the most important theme reported by participants in order to improve the quality of health services at the clinics in Malaysia. followed by the attitude of healthcare professionals (n= 9, 3%), the long waiting hours (n= 6, 2%), and the poor wound assessment (n= 2, 0.7%). Meanwhile, one patient commented regarding follow-ups, the availability of up-to-date information, and the high cost of treatment respectively.

Table 4. 55 Responses of open-ended questions

Themes	Frequency	Percentage
Others - “good services”, “everything was excellent”, “nothing to complain about” and “no suggestions”	260	87
Staffing	20	6.7
The attitude of healthcare professionals	9	3
The long waiting hours	6	2
The poor wound assessment	2	0.7
Follow-up	1	0.3
The high cost of treatment	1	0.3
The availability of up-to-date information	1	0.3
Total	**300**	**100.0**

4.12 Summary

This chapter presented the findings of the statistical analyses performed to address the six research questions.

Inferential analysis showed that there was a significant association between diabetic foot ulcer pain and gender, marital status, duration of diabetes mellitus, comorbidities, number of foot ulcer episode, site of foot ulcer, severity of foot ulcer, type of cleaning solution, and type of dressing.

In relation to the association between diabetic foot ulcer pain and seven SF-36 subscales, significant negative correlations with diabetic foot ulcer pain were reported; these subscales were SF-36 role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Furthermore, all subscales in DFS-SF had significant negative correlations with diabetic foot ulcer pain. In addition, functional status (Katz ADL and Lawton IADL) had a statistically negative relationship with diabetic foot ulcer pain.

A stepwise multiple regression analysis was used to analyse significant predictors of diabetic foot ulcer pain. Being female, having a Grade 4 foot ulcer, using sterile water, using antimicrobial dressing, experiencing bodily pain and being bothered by ulcer care were significant predictors of the diabetic foot ulcer pain and accounted for 52% of variability in diabetic foot ulcer pain.

Analysis of the answers to the open-ended question revealed seven themes regarding comments or suggestions to improve the quality of health services at

the clinic. The themes are staffing, long waiting hours, follow-ups, the attitude of healthcare professionals, poor wound assessment, availability of up-to-date information, and the high cost of treatment.

The next chapter will discuss the similarities and differences between Clinic S and Clinic P.

CHAPTER 5

RESULTS

5.1 Introduction

This is the second chapter that reports the findings from the current study. This chapter will provide information about the details of similarities and differences between Clinic S and Clinic P.

5.2 Participants' recruitment in Clinic S and Clinic P

A total of 178 patients aged 60 years and above with diabetic foot ulcers were invited to participate in the study in Clinic S. Two of them, however, refused to take part. Hence, the total number of participants who gave consent and participated in the study in Clinic S was 176 (response rate= 99%). In contrast, in Clinic P, 124 patients aged 60 years and above with diabetic foot ulcers were invited to participate in the study, and all of them participated in the study. The response rate was 100%.

5.3 Socio-demographic characteristics of the participants.

5.3.1 Age and gender

The age and gender of the participants in the both clinics are presented in Table 5.1. The mean age of Clinic S participants was 65.32 years (SD= ±5.19), while the mean age of Clinic P participants was 65.01 years (SD= ±4.67).

In both clinics, the majority of the participants were in the age range of between 60 to 69 years old (n= 143, 81.3 %: n= 104, 83.9% respectively), followed by the 70 to 79 years old age group (n= 29, 16.5 %) in Clinic S and 19 participants (15.3%) in Clinic P. Only four participants (2.3%) were aged 80 years old and above in Clinic S and one participant (0.8%) in Clinic P.

In terms of gender, the results from Clinic S were similar to those from Clinic P, where male participants outnumbered female participants (n= 89, 50.6%: n= 75, 60.5 % respectively).

Table 5. 1 Age and gender participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Range**	**Mean ± SD**	**Range**	**Mean ± SD**
Age in years	60 - 88	65.32 ± 5.19	60 - 80	65.01 ± 4.67
	Frequency	**Percentage**	**Frequency**	**Percentage**
Age categories				
60 to 69	143	81.3	104	83.9
70 to 79	29	16.5	19	15.3
80 and above	4	2.3	1	0.8
Total	**176**	**100.0**	**124**	**100.0**
Gender				
Male	89	50.6	75	60.5
Female	87	49.4	49	39.5
Total	**176**	**100.0**	**124**	**100.0**

5.3.2 Race and religion

Table 5.2 presents details of race and religion in both clinics. As the table illustrates, the frequency for race distributions was comparable across both clinics. Malay participants were the main attendees in both clinics (n= 88, 50.0%: n= 53, 42.7% respectively), followed by Indians and others (n= 59, 33.5%) and Chinese (n= 29, 16.5%) in Clinic S and Chinese (n= 45, 36.3%) and Indian and others (n= 26, 21.0%) in Clinic P.

The majority of participants in Clinic S were Muslim (n= 88, 50.0%), followed by Hindu (n= 51, 29%), Buddhist (n= 30, 17%) and Christian and other (n= 7, 4.0%). While in Clinic P, the majority were Muslim (n= 53, 42.7%), followed by Buddhist (n= 43, 34.7%), Hindu (n= 22, 17.7%) and Christian and other (n= 6, 4.8%).

Table 5. 2 Race and religion of participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Race				
Malay	88	50.0	53	42.7
India+ other	59	33.5	26	21.0
Chinese	29	16.5	45	36.3
Total	**176**	**100.0**	**124**	**100.0**
Religion				
Muslims	88	50.0	53	42.7
Buddhist	30	17.0	43	34.7
Hindu	51	29.0	22	17.7
Christian+ other	7	4.0	6	4.8
Total	**176**	**100.0**	**124**	**100.0**

5.3.3 Marital status

Table 5.3 shows the marital status of the participants in both clinics. Most participants in both clinics were married (n= 132, 75%: n= 85, 68.5% respectively), followed by widowed, divorced or separated (n= 37, 21%: n= 33, 26.6%). Only seven participants (4.0%) were single in Clinic S and six participants (4.8%) in Clinic P.

Table 5. 3 Marital status participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Marital Status				
Married	132	75.0	85	68.5
Widowed + divorced + separated	37	21.0	33	26.6
Single	7	4.0	6	4.8
Total	**176**	**100.0**	**124**	**100.0**

5.3.4 Educational level

Table 5.4 illustrates the distribution of educational level in both clinics. The majority of participants in Clinic S had received secondary education (n= 103, 58.5%), followed by primary education (n=46, 26.1%), tertiary education (n= 18, 10.2%), and never been to school (n= 9, 5.1%).

In contrast, in Clinic P the majority of participants had received primary education (n= 58, 46.8%), followed by secondary education (n= 54, 43.5%), tertiary education (n= 7, 5.6%) and never been to school (n= 5, 4.0%).

Table 5. 4 Educational level participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Educational Level				
Secondary education	103	58.5	54	43.5
Primary education	46	26.1	58	46.8
Tertiary education	18	10.2	7	5.6
Never	9	5.1	5	4.0
Total	**176**	**100.0**	**124**	**100.0**

5.3.5 Number of floors in the house

Table 5.5 shows the number of floors in the houses of the participants in both clinics. Most of participants in both clinics stayed in a house with additional floors (n= 114, 64.8%: n= 65, 52.4%) in Clinic S and Clinic P respectively, while, (n= 62, 35.2%) in Clinic S and (n= 59, 47.6%) in Clinic P reported having no additional floors.

Table 5. 5 Number of floors in the homes of participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Number of floors				
Home with additional floors (1½ floors, 2 floors, 2 ½ floors and 3 floors and above)	114	64.8	65	52.4
Home without additional floors (1 floor)	62	35.2	59	47.6
Total	**176**	**100.0**	**124**	**100.0**

5.4 Clinical characteristic of the participants

5.4.1 Duration of having diabetes mellitus

Participants were asked to state the duration of their diabetes mellitus. As illustrated in Table 5.6, the duration of diabetes ranged from 0.2 to 35 years with a median duration of 20 years (IQR= 15) in Clinic S. In contrast, in Clinic P, the duration of diabetes ranged from 0.5 to 35 years with a median duration of 17 years (IQR= 15).

Table 5. 6 Duration of diabetes (in years) for participants in Clinic S and Clinic P

	Clinic S				**Clinic P**			
Variables	**Median (IQR)**	**Range**	**Mean**	**± SD**	**Median (IQR)**	**Range**	**Mean**	**± SD**
Duration of diabetes in years	20.0 (15.0)	0.25 – 35	17.9	8.45	17.0 (15.0)	0.5 - 35	16.8	8.75

Note: IQR =Interquartile range

5.4.2 Number of other co-morbidities besides diabetes, present at the time of the study

Table 5.7 shows other health problems associated with the participants at the time of the study in both clinics. In Clinic S, 47.2% (n=83) of participants reported that they had one additional health problem apart from diabetes, followed by 27.8% (n= 49) of participants, who reported having two additional health problems, and 7.4% (n= 13) of participants, who reported having more than three health problems. Meanwhile, 17.6% (n= 31) of participants reported having no other health problems except diabetes. A similar pattern was observed in Clinic P, where nearly 40% (n= 49) reported having one additional health problem apart from diabetes, followed by 32.3% (n= 40) of participants, who reported having two additional health problems, and 19.4% (n= 24) of participants, who reported having more than three health problems. Only 8.9% (n=11) participants reported having no other health problems except diabetes.

Table 5. 7 Number of other co-morbidities besides diabetes in participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Number of other co- morbidities				
1	83	47.2	49	39.5
2	49	27.8	40	32.3
0	31	17.6	24	19.4
>3	13	7.4	11	8.9
Total	**176**	**100.0**	**124**	**100.0**

5.4.3 Types of diabetes treatment

Types of diabetes treatment received by the participants in both clinics are presented in Table 5.8. In Clinic S, the majority of the participants were on insulin therapy (n= 80, 45.5%), while another 48 (27.3%) were on oral hypoglycaemia agents. 26 participants (14.8%) were on both insulin and oral hypoglycaemia agents. Only 22 participants were on diet control alone (12.5%). A similar pattern was observed in Clinic P where most of the participants on insulin therapy (n= 29, 55.6%), followed by oral hypoglycaemia agents (n= 32, 25.8%), both insulin and oral hypoglycaemia agents (n= 18, 14.5%) and diet control alone (n= 5, 4.0%).

Table 5. 8 Types of diabetes treatment participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Types of diabetes treatment				
Insulin therapy	80	45.5	69	55.6
Oral hypoglycaemia agents	48	27.3	32	25.8
Both insulin and oral hypoglycaemia agents	26	14.8	18	14.5
Diet control only	22	12.5	5	4.0
Total	**176**	**100.0**	**124**	**100.0**

5.4.4 Foot ulcer episode

Foot ulcer episodes in both clinics are presented in Table 5.9. The majority of the participants in both clinics were experiencing a first episode of foot ulcer (n= 105, 59.7%: n= 67, 54% respectively), followed by those experiencing a second episode of foot ulcer (n= 52, 29.5%: n= 46, 37.1%) and those experiencing a third episode of foot ulcer (n= 11, 6.3%: n= 8, 6.5%), while eight (4.5%) participants in Clinic S had experienced more than three episodes of foot ulcer compared to three (2.4%) in Clinic P.

Table 5. 9 Foot ulcer episode participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Foot ulcer episode				
1st episode	105	59.7	67	54.0
2nd episode	52	29.5	46	37.1
3rd episode	11	6.3	8	6.5
More than 3 episodes	8	4.5	3	2.4
Total	**176**	**100.0**	**124**	**100.0**

5.4.5 Duration of foot ulcer episodes

Participants were asked to state the duration of their foot ulcer episode. As illustrated in Table 5.10, the duration of foot ulcer episodes ranged from 1 to 96 months with a median duration of 4 months (IQR= 10) in Clinic S. A similar pattern was observed in Clinic P where the duration of foot ulcer episodes ranged from 1 to 96 months with a median duration of 3 months (IQR= 5).

Table 5. 10 Duration of foot ulcer episode in months for participants in Clinic S and Clinic P

	Clinic S				**Clinic P**			
Variables	**Median (IQR)**	**Range**	**Mean**	**± SD**	**Median (IQR)**	**Range**	**Mean**	**± SD**
Duration of foot ulcer in months	4 (10)	1 - 96	9.05	13.74	3 (5)	1 - 96	6.59	11.02

Note: IQR =Interquartile range

5.4.6 Site of foot ulcer

In relation to the site of foot ulcers, the site of the foot ulcer in most of the participants in Clinic S was at midfoot (n= 83, 47.1%), whereas in Clinic P only 59 (47.6%) participants were in this category, followed by at forefoot (n= 61, 34.7%: n=33, 26.6%) and at hindfoot (n=32, 18.2%: n= 32, 25.8%). Table 5.11 shows the site of foot ulcer formation in both clinics.

Table 5. 11 Site of foot ulcer participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Site of foot ulcer				
Midfoot	83	47.1	59	47.6
Forefoot	61	34.7	33	26.6
Hindfoot	32	18.2	32	25.8
Total	**176**	**100.0**	**124**	**100.0**

5.4.7 Severity of foot ulcer

The severity of diabetic foot ulcers was classified using the Wagner wound classification system (Wagner 1981). The most common stages of ulcer in Clinic S were grade 2 (n= 79, 44.8%), grade 1 (n= 47, 26.7%), grade 3 (n= 43, 24.4%) and grade 4 (n= 7, 3.9%). Contrary to this in Clinic P, 52.4% (n= 65) were grade 1, followed by grade 2 (n=39, 31.5%), grade 3 (n= 16, 12.9%), and grade 4 (n= 4, 3.2%). Table 5.12 identifies the Wagner wound classification of the participants in both clinics.

Table 5. 12 Wagner wound classification (1981) participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Wagner wound classification				
Grade 1	47	26.7	65	52.4
Grade 2	79	44.8	39	31.5
Grade 3	43	24.4	16	12.9
Grade 4	7	3.9	4	3.2
Total	**176**	**100.0**	**124**	**100.0**

5.4.8 The perceived cause of diabetic foot ulcers

The perceived causes of the diabetic foot ulcers identified by the participants in both clinics are summarised in Table 5.13. In Clinic S, the majority of the participants perceived that the main cause of their foot ulcer was injury (n= 104, 59.1%), followed by no evidence of cause (n= 34, 19.3%), spontaneous blister (n= 26, 14.8%), improperly fitting footwear (n= 8, 4.5%) and burns (n= 4, 2.3%).

In contrast, in Clinic P, the majority of the participants perceived that the main cause of their foot ulcer was injury (n= 79, 63.7%), followed by spontaneous blister (n= 22, 17.7%), improperly fitting footwear (n= 12, 9.7%), no evidence of cause (n= 10, 8.1%), and fungal infection (n= 1, 0.8%).

Table 5. 13 The perceived cause of diabetic foot ulcers as perceived by participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
The perceived cause of foot ulcer				
Injury	104	59.1	79	63.7
Spontaneous blister	26	14.8	22	17.7
No evidence of cause	34	19.3	10	8.1
Improperly fitting foot wear	8	4.5	12	9.7
Burns	4	2.3	0	0
Fungal infection	0	0	1	0.8
Total	**176**	**100.0**	**124**	**100.0**

5.4.9 Frequency of dressing change

Regarding the frequency of dressing change, the majority of the participants in Clinic S reported having their dressing changed when needed (n= 84, 47.7%), 21% of the participants (n= 37) had their dressing changed once a week, 19.8% (n= 35) had their dressing changed every alternate day and 11.3% (n= 20) had their dressing changed on a daily basis.

In Clinic P, the frequency of dressing change was varied, but the most extensively was reported on a daily basis (n= 100, 80.7%), 11.3% of the participants (n= 14) had their dressing changed when needed, 4% (n= 5) had their dressing changed once a week, and 4% (n= 5) had their dressing changed on alternate days. Table 5.14 identifies the frequency of dressing change in both clinics.

Table 5. 14 Frequency of dressing participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Frequency of dressing				
Daily	20	11.3	100	80.7
When Needed	84	47.7	14	11.3
Once a week	37	21.0	5	4.0
Every alternate day	35	19.8	5	4.0
Total	**176**	**100.0**	**124**	**100.0**

5.4.10 Type of cleaning solution

The type of cleaning solution used by participants in both clinics is shown in Table 5.15. The majority of the participants in Clinic S (n= 54, 30.7) used Prontosan as their cleaning solution. Nearly 30% (n= 49) used Dermacyn, 25% (n= 44) used Hydrocyn, 9.7% (n= 17) used saline, and 6.8% (n= 12) used sterile water.

Meanwhile, the majority of participants in Clinic P (n= 84, 67.8) used saline as their cleaning solution; 13.8% of the participants (n= 17) used Hydrocyn, 12% (n= 15) used Dermacyn, 4% (n= 5) used Prontosan and 2.4 % (n= 3) used sterile water.

Table 5. 15 Type of cleaning solution used by participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Type of cleaning solution				
Saline	17	9.7	84	67.8
Dermacyn	49	27.8	15	12.0
Hydrocyn	44	25.0	17	13.8
Prontosan	54	30.7	5	4.0
Sterile water	12	6.8	3	2.4
Total	**176**	**100.0**	**124**	**100.0**

5.4.11 Type of dressing

Regarding the type of dressing, the majority (n= 147, 83.5%) of the participants in Clinic S used a gel dressing as their dressing type, followed by dry gauze (n= 12, 6.8%), foam (n= 11, 6.2%), wet saline soaked, and antimicrobials (n= 3, 1.7%) respectively.

Meanwhile, the majority of the participants in Clinic P (n= 87, 70.1%) used gel dressing as their dressing type; 19.3% of the participants (n= 24) used dry gauze, 5.6 %% (n= 7) used antimicrobials, 3.2% (n= 4) used foam, and 1.6 % (n= 2) used wet saline soaked. Table 5.16 identifies the type of dressing in both clinics.

Table 5. 16 Type of dressing participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Type of dressing				
Gel	147	83.5	87	70.1
Dry gauze	12	6.8	24	19.3
Foam	11	6.2	4	3.2
Antimicrobials	3	1.7	7	5.6
Wet saline soaked	3	1.7	2	1.6
Total	**176**	**100.0**	**124**	**100.0**

5.4.12 Self-management strategies

The participants in both clinics were asked about which was the most important self-management strategy to reduce pressure at their foot ulcer (see Table 5.17). In Clinic S, the most frequently used strategy was resting the foot, which accounted for 31.8% (n= 56) of the participants. This was followed by diabetic sandals, which was used by 23.9% (n=42) of the participants; restriction of mobility level 20.5% (n= 36); non-weight bearing walking with crutches (n=8, 4.5%); the use of back slap and orthosis (n=3, 1.7% each); and the use of insole and wheelchair (n=2, 1.1% each).

The most frequently used strategy in Clinic P was resting the foot, which accounted for 33.1% (n= 41) of the participants. This was followed by restriction of mobility level, which was used by 24.2% (n= 30) of the participants; elevation of limb (n= 26, 21.0%); diabetic sandal (n=20, 16.1%); non-weight bearing walking with crutches (n=3, 2.4%); insole (n=2, 1.6%); and the use back slap and total contact cast (n=1, 0.8% each).

Table 5. 17 Most important self-management strategies mentioned by each participant in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Self-management strategies				
Foot rest	56	31.8	41	33.1
Restriction of mobility level	36	20.5	30	24.2
Diabetic sandal	42	23.9	20	16.1
Elevation of limb	26	21.0	26	21.0
Non-weight bearing walking crutches	8	4.5	3	2.4
Insole	2	1.1	2	1.6
Back slab	3	1.7	1	0.8
Total contact cast	0	0	1	0.8
Orthosis	3	1.7	0	0
Wheelchair	2	1.1	0	0
Total	**176**	**100.0**	**124**	**100.0**

5.4.13 Surgical intervention/procedures

Regarding surgical intervention or procedures related to foot ulcers, in Clinic S, nearly half of the participants (n=73, 41.5%) had undergone debridement, followed by ray amputation (n= 23, 13.1%), below-knee amputation (n= 10, 5.7%), toe amputation and forefoot amputation (n= 6, 3.4% each), above-knee amputation (n= 3, 1.1%) and skin graft (n=1, 0.6%). Meanwhile, slightly more than one third of the participants (n= 73, 41.5%) did not undergo any surgical intervention or procedure.

In contrast to this, in Clinic P, most of the participants reported not having undergone any surgical intervention or procedure (n= 54, 39.5%), followed by debridement (n= 49, 39.5%), toe amputation (n= 6, 4.8%), ray amputation (n= 5, 4.0 %), skin graft (n= 4, 3.2 %), and forefoot amputation and above-knee amputation (n= 1, 0.8% each). The distribution of surgical intervention/procedures related to foot ulcers for both clinics is shown in Table 5.18.

Table 5. 18 Surgical intervention/procedures participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Surgical intervention/procedures				
Debridement	73	41.5	49	39.5
None	55	31.3	54	43.5
Ray amputation	23	13.1	5	4.0
Below knee amputation	10	5.7	4	3.2
Toe amputation	6	3.4	6	4.8
Forefoot amputation	6	3.4	1	0.8
Skin graft	1	0.6	4	3.2
Above knee amputation	2	1.1	1	0.8
Total	**176**	**100.0**	**124**	**100.0**

5.4.14 Pain relief use

Most participants in Clinic S, 97 (55.1%) reported not having taken any pain relief while 50.8% (n=63) of the participants in primary care reported having taken pain relief for their wound pain.

The participants in both clinics who had taken pain relief reported that they perceived it to be effective in relieving their pain. The pain relief use of the participants in the study is presented in Table 5.19.

Table 5. 19 Pain relief use by participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Do you take pain relief for your pain?				
No	97	55.1	61	49.2
Yes	79	44.9	63	50.8
Total	**176**	**100.0**	**124**	**100.0**
Does medication relieve your pain?				
Yes	79	44.9	63	50.8
Total	**176**	**100.0**	**124**	**100.0**

5.5 Comparison pain experiences between participants in Clinic S and Clinic P.

As mentioned previously in Chapter 3 and Chapter 4, pain experiences were assessed with the SF-MPQ.

5.5.1 Comparison descriptive analysis of the short-form McGill pain questionnaire scores between participants in Clinic S and Clinic P.

The descriptive data derived from the SF-MPQ are show in Table 5.20. In the SF-MPQ, the total PRI showed a slightly higher median score in the Clinic S group (medium= 6.50, IQR= 9) compared to the Clinic P group (medium= 6, IQR= 7). This showed that the participants in Clinic S experienced more pain compared to the participants in Clinic P.

Similarly, in both clinics, participants more commonly endorsed the sensory descriptors of pain quality than they did the affective descriptors with median (IQR) PRI values of 5.50 (7) and 1 (3) respectively in Clinic S, and 5 (6) and 1 (2) respectively in Clinic P.

Table 5. 20 Short- form McGill pain questionnaire scores participants in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**
PRI - Total	6.50 (9)	0 - 45	1- 41	9.95	8.87	6 (7)	0 - 45	1- 41	8.55	7.31
PRI - Sensory	5.50 (7)	0 - 33	0- 33	7.91	7.08	5 (6)	0 - 33	0- 29	6.82	5.45
PRI - Affective	1 (3)	0 - 12	0- 12	2.05	2.66	1 (2)	0 - 12	0- 12	1.73	2.54

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range
PRI – Total = Pain Rating Index Total; PRI – Sensory = Pain Rating Index Sensory; Affective PRI= Pain Rating Index

5.5.2 Verbal descriptor chosen to describe the quality of pain in the short-form McGill pain questionnaire between participants in Clinic S and Clinic P

Rank ordered descriptor use frequencies for the participants are presented in Table 5.21. Sensory words most commonly used to describe diabetic foot ulcer-related pain in both clinics were throbbing (n= 148, 84%; n= 107, 86.2%), shooting (n= 124, 70.4%; n= 89, 72%), aching (n= 120, 68.1%, n= 85, 69%), stabbing (n= 81, 46%; n= 65, 52.4%), and cramping (n= 85, 48.2%; n= 53, 43%) respectively. The affective descriptor most commonly to describe diabetic foot ulcer-related pain in both clinics were tiring exhausting (n= 80, 45.4% n= 46, 37%) and fearful (n= 57, 27% n= 43, 35%) in Clinic S and Clinic P respectively.

Table 5. 21 Rank ordered descriptor use frequencies of the short-form McGill pain questionnaire in participants in Clinic S and Clinic P

Variables	Frequency	Percentage	Frequency	Percentage
	Clinic S		Clinic P	
Sensory				
Throbbing	148	84.0	107	86.2
Shooting	124	70.4	89	72.0
Aching	120	68.1	85	69.0
Stabbing	81	46.0	65	52.4
Cramping	85	48.2	53	43.0
Tender	65	37.0	42	34.0
Heavy	60	34.0	36	29.0
Sharp	53	30.0	41	33.0
Hot-burning	34	19.3	20	16.1
Gnawing	35	20.0	18	15.0
Splitting	31	18.0	15	12.0
Affective				
Tiring exhausting	80	45.4	46	37.0
Fearful	57	27.0	43	35.0
Punishing cruel	45	26.0	36	29.0
Sickening	38	22.0	27	22.0

5.5.3 Visual analogue scale score between participants in Clinic S and Clinic P

Table 5.22 displays the VAS; the results showed that the pain experienced ranged from 0 to 88.54 mm with a median of 35.93 (IQR= 29.17) in Clinic S compared to Clinic P where the pain experienced ranged from 8.3 to 92.7 mm with a median of 35.41 mm (IQR= 28.91).

Table 5. 22 The visual analogue score participants in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**
VAS - pain intensity	35.93 (29.17)	0 -100 mm	0- 88.54	39.00	1.56	35.41 (28.91)	0 -100 mm	8.3- 92.7	39.07	1.69

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range; VAS = Visual Analogue Scale

5.5.4 Comparison present pain index between participants in in Clinic S and Clinic P

Table 5.23 PPI that is in the third part of the SF-MPQ, which describes the present pain that the participants were feeling at the time of answering the questionnaire. There were six descriptors of pain listed in the form ranging from no pain to excruciating. Most participants in both clinics rated their evaluative overall diabetic foot ulcer pain as mild (n= 67, 38%; n= 62, 50%), followed by discomforting (n= 63, 36%; n= 41, 33.1%), distressing (n= 29, 17%; n= 14, 11.3%), no pain (n= 10, 6%; n= 4, 3.2%), and finally horrible (n= 7, 4%; n= 3, 2.4%) respectively.

Table 5. 23 Descriptor of present pain index for participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Mild	67	38.0	62	50.0
Discomforting	63	36.0	41	33.1
Distressing	29	17.0	14	11.3
No pain	10	6.0	4	3.2
Horrible	7	4.0	3	2.4
Total	**300**	**100.0**	**300**	**100.0**

5.6 Comparison health-related quality of life between participants in Clinic S and Clinic P.

As mentioned previously in Chapter 3 and Chapter 4, health-related quality of life was assessed using the SF-36 and DFS-SF.

5.6.1 Health-related quality of life measured using the medical outcomes study 36- item short-form health survey

Table 5. 24 displays the SF-36 scores for the participants in both clinics. In Clinic S, the physical health summary score was lower than the mental health summary score (mean= 45.55, SD = 14.60, range = 15 to 85 and 60.10, 14.04, 31, 75-88.50) respectively.

However, each domain in the SF-36 in Clinic S was scored higher than the norm of 50 except for physical functioning (mean = 32.27, SD = 22.58, range = 5-100), physical role (mean = 49.58, SD = 21.95, range 12.5 to 100), and general health (mean = 42.58, SD = 12.73, range 10 to 90).

A similar pattern was observed in Clinic P where physical functioning (mean = 36.16, SD = 22.11, range = 5-100), physical role (mean = 49.91, SD = 18.93, range 12.5 to 100), and general health (mean = 42.57, SD = 11.08, range 20 to 80) was scored higher than the norm of 50.

In summary, the results suggest that the participants in both clinics had poor health-related quality of life in the physical functioning, physical role, and general health domains.

Table 5. 24 The medical outcomes study 36- item health survey short- form scores for participants in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**
SF-36 Physical health summary	**43.75 (18.28)**	**0-100**	**15-85**	**45.55**	**14.60**	**45.62**	**0-100**	**18.75-85.31**	**46.58**	**13.74**
Physical functioning	27.50 (38.75)	0-100	5- 100	32.27	22.58	30 (30)	0-100	5- 100	36.16	22.11
Physical role	50 (37.19)	0-100	12.50-100	49.91	21.95	50 (29.69)	0-100	12.50- 100	49.58	18.93
Bodily pain	55 (25)	0-100	10- 100	57.45	21.34	55 (22.5)	0-100	10- 100	58.00	19.62
General health	40 (10)	0-100	10- 90	42.58	13.80	40 (10)	0-100	20- 80	42.57	11.08
SF-36 Mental health summary	**60.25 (21.25)**	**0-100**	**31.75-88.50**	**60.10**	**14.04**	**59.87 (20.34)**	**0-100**	**28.00-90.00**	**59.71**	**14.03**
Vitality	50 (15)	0-100	10- 90	51.10	13.91	50 (10)	0-100	10- 80	51.45	13.59
Social functioning	50 (25)	0-100	12.50-100	58.90	21.52	50 (25)	0-100	12.50- 100	57.84	20.12
Emotional role	75 (50)	0-100	25-100	66.25	25.51	75 (50)	0-100	16.67-100	67.51	25.77
Mental health	64 (20)	0-100	28- 88	64.13	14.73	60 (20)	0-100	24- 88	62.03	12.62

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range

5.6.2 Health-related quality of life measured using the diabetic foot ulcer scale short form

In the DFS-SF, all the components showed higher mean scores in Clinic P compared to Clinic S except for the component negative emotions (mean= 75.04, SD = 25.32) in Clinic S and (mean= 71.87, SD = 25.26) in Clinic P and bothered by ulcer care (mean= 70.77, SD = 26.23) in Clinic S and (mean= 67.94, SD = 23.98) in Clinic P. Table 5.25 shows the result of the DFS-SF in both clinics.

Table 5. 25 Diabetic foot ulcer scale short form scores for participants in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**
Leisure	47.5 (35)	0-100	0- 100	41.67	29.36	50 (50)	0-100	0-100	44.55	28.93
Physical health	55 (30)	0-100	0- 100	53.72	20.85	60 (20)	0-100	0- 100	56.85	20.14
Dependence/ daily life	55 (40)	0-100	0- 100	51.36	27.33	55 (30)	0-100	10-100	56.04	23.19
Negative emotions	75 (40.63)	0-100	0- 100	75.04	25.32	75 (41.67)	0-100	0- 100	71.87	25.26
Worried about ulcers/feet	30.77 (45.19)	0-100	0- 61.54	25.84	22.69	23.08 (34.62)	0-100	0- 61.54	27.17	20.17
Bothered by ulcer care	75 (43.75)	0-100	0-100	70.77	26.23	68.75 (42.19)	0-100	0-100	67.94	23.98

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range

5.7 Comparison functional status between participants in Clinic S and Clinic P.

As discussed in Chapters 3 and Chapter 4, functional status was assessed using the Katz ADL and Lawton IADL.

5.7.1 Functional status measured using the Katz activity of daily living

Table 5.26 illustrates the Katz ADL in both clinics. The participants in Clinic S had scores ranging from 0 to 6 (median = 6; IQR = 0). Meanwhile, in Clinic P, the participants had scores ranging from 2 to 6 (median = 6; IQR = 0). The majority of participants in both clinics had scores of 6/6, indicating independence in activities of daily living.

Table 5. 26 Katz activity of daily living scores for participants in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**
Katz activity of daily living	6 (0)	0 - 6	0- 6	5.58	1.14	6 (0)	0 - 6	2- 6	5.70	0.75

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range

5.7.2 Functional status measured using the Lawton instrumental activities of daily living

In Table 5.27, the Lawton IADL showed comparable results in both clinics. The participants in both clinics had a median score of 7 (IQR= 2) with scores ranging from 3 to 8. The majority of the participants in both clinics had scores of 7/8 or 8/8, indicating independence in instrumental activities of daily living.

Table 5. 27 Lawton instrumental activities of daily living score participants in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**	**Median (IQR)**	**Possible range**	**Range**	**Mean**	**± SD**
Lawton instrumental activities of daily living	7 (2)	0 - 8	3- 8	6.58	1.22	7 (2)	0 - 8	3- 8	6.64	1.27

Note: Plus-minus values are ± Standard deviation (SD), IQR =Interquartile range

5.8 Comparison of association between pain and selected socio-demographic characteristic, selected clinical characteristic health-related quality of life and functional status between participants in Clinic S and Clinic P.

5.8.1 Association between pain and socio-demographic variables

5.8.1.1 Association between pain and gender

Table 5.28 shows the association between pain and gender in Clinic S and Clinic P as investigated using the Mann-Whitney U test. There was a significant difference in the SF-MPQ scores and gender ($z = -3.56$, $p < 0.001$) for the participants from Clinic P. Thus, based on the median value score, the female participants had obtained the highest median value on the SF-MPQ scores compared to male participants, indicating the level of pain was worse in the female participants than in the males. However, there were no significant differences between pain and gender for the participants from Clinic S.

Table 5. 28 Comparison of the short-form McGill pain questionnaire scores and gender in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**z-value**	**p-value**	**Median**	**IQR**	**Mean rank**	**z-value**	**p-value**
Gender				-1.85	0.065				-3.56	<0.001*
Male	6.00	6.00	81.50			5.00	5.00	53.25		
Female	8.00	12.00	95.66			8.00	11.00	76.65		

Note: z = Man Whitney U test, IQR =Interquartile range * Indicated statistically significant result.

5.8.1.2 Association between pain and number of floor in the house

In Table 5.29, to determine whether there was any difference in the SF-MPQ scores in those participants with homes with with additional floors and homes without additional floors, the Mann-Whitney U test. However, there were no significant differences in the scores for homes with additional floors and homes without additional floors in relation to pain between both settings (z= -0.64, p=0.521; z=-0.71, p=0.475 respectively).

Table 5. 29 Comparison of the short-form McGill pain questionnaire scores and number of floors in the house in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**z- value**	**p- value**	**Median**	**IQR**	**Mean rank**	**z- value**	**p- value**
Number of floors				-0.64	0.521				-0.71	0.475
Home with additional floors (1½ floors, 2 floors, 2 ½ floors and 3 floors and above)	6.00	9.00	86.69			6.00	6.50	60.32		
Home without additional floors (1 floor)	7.00	10.50	91.83			6.00	10.00	64.91		

Note: Note: z = Man Whitney U test, IQR =Interquartile range

5.8.1.3 Association between pain and age categories

The Kruskal-Wallis test was used to examine the association between the SF-MPQ scores and age categories. In Table 5.30, the participants were divided into three groups according to their age (Group 1: 60-69 years, Group 2: 70-79 years, Group 3: 80 and above. There was no statistically significant difference in the SF-MPQ scores and age categories between both settings (X^2= 2.66, p=0.264; X^2= 0.76, p=0.683) respectively.

Table 5. 30 Comparison of the the short-form McGill pain questionnairescores and age categories in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Age				2.66	0.264				0.76	0.683
60-69	7.00	10.00	91.47			6.00	7.75	62.63		
70-79	6.00	7.50	76.40			6.00	7.00	63.39		
80 and above	5.50	7.00	70.0			-	-	-		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

5.8.1.4 Association between pain and race

The association between the SF-MPQ scores and race was examined using the Kruskal-Wallis test. Participants were divided into three groups according to their race (Group 1: Malay, Group 2: Chinese, Group 3: India + other. There was no statistically significant difference in the SF-MPQ scores and race between both settings (X^2= 4.20, p=0.122; X^2=2.55, p=0.279 respectively) (see Table 5.31).

Table 5. 31 Comparison of the short-form McGill pain questionnaire scores and race in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Race				4.20	0.122				2.55	0.279
Malay	7.50	11.00	87.97			8.00	10.00	67.50		
Chinese	6.00	3.00	73.22			6.00	6.50	61.56		
India+ other	6.00	10.00	96.80			5.00	4.50	53.94		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

5.8.1.5 Association between pain and religion

In terms of religion, the participants were divided into four groups according to their religion. (Group 1: Muslim, Group 2: Buddhist, Group 3: Hindu, Group 4: Christian + other). The Kruskal-Wallis test in Table 5.32 suggests that there was no statistically significant difference in the SF-MPQ scores and religion between both settings (X^2= 3.77, p=0.288; X^2=2.02, p=0.0.567 respectively).

Table 5. 32 Comparison of the short-form McGill pain questionnaire scores and religion in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Religion				3.77	0.288				2.02	0.567
Muslims	7.00	11.00	87.85			8.00	10.00	67.50		
Buddhist	6.00	3.25	74.78			5.00	6.00	60.13		
Hindu	6.00	10.00	95.79			5.50	4.50	55.82		
Christian+ other	6.00	15.00	102.29			5.50	11.00	59.83		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

5.8.1.6 Association between pain and marital status

Table 5.33 presents the association between the SF-MPQ scores and marital status. The Kruskal-Wallis test was used. The participants were divided into three groups according to marital status (Group1: married, Group 2: widowed + divorced + separated, Group 3: single). There was no statistically significant difference in the SF-MPQ scores and marital status between both settings (X^2= 5.64, p=0.060; X^2=2.65, p=0.266 respectively).

Table 5. 33 Comparison of the short-form McGill pain questionnaire scores and marital status in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Marital Status				5.64	0.060				2.65	0.266
Married	7.00	10.00	92.81			6.00	7.50	63.22		
Widowed+ divorced+ separated	6.00	8.50	80.11			6.00	7.50	64.82		
Single	3.00	4.00	51.64			4.00	3.75	39.50		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

5.8.1.7 Association between pain and educational level

The association between pain and educational status was examined using non-parametric testing (Kruskal-Wallis test) because the data were not distributed normally. The participants in both settings were divided into four groups according to their educational status (Group 1: secondary, Group 2: primary, Group 3: tertiary, Group 4: never). Again, there was no statistically significant difference in the SF-MPQ scores and educational level between both settings (X^2= 4.17, p=0.244; X^2=0.47, p=0.925 respectively). The result is presented in Table 5.34.

Table 5. 34 Comparison of the short-form McGill pain questionnaire scores and educational level in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Educational Level				4.17	0.244				0.47	0.925
Secondary education	7.00	10.00	89.53			5.00	9.25	60.07		
Primary education	7.00	8.25	92.91			6.00	6.25	64.66		
Tertiary education	4.00	5.00	66.31			5.00	17.00	62.14		
Never	8.00	24.5	98.50			7.00	6.50	64.2		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range

5.8.2 Association between pain and clinical variables

5.8.2.1 Association between pain and duration of having diabetes mellitus

Association between pain and duration of diabetes mellitus was examined using non-parametric testing with Spearman's rank correlation coefficient because of the not normal distribution. Table 5.35 summarises the correlations with the SF-MPQ scores and the duration of diabetes mellitus. This table shows that for the Clinic S participants, the duration of diabetes mellitus had a statistically significant negative correlation with the SF-MPQ scores (Spearman's rank correlation coefficient (p)= -0.21, p=0.005). However, there was no significant correlation between pain and the duration of diabetes mellitus for the Clinic P participants.

Table 5. 35 Comparison of the short-form McGill pain questionnaire scores and duration of diabetes mellitus in Clinic S and Clinic P.

	Clinic S		**Clinic P**	
Variables	**Spearman's rank correlation coefficient p**	**p-value**	**Spearman's rank correlation coefficient p**	**p-value**
Duration of diabetes mellitus	-0.21	0.005*	0.05	0.612

5.8.2.2 Association between pain and duration of diabetic foot ulcer

Table 5.36 summarises the correlations with the SF-MPQ scores and the duration of the diabetic foot ulcers. The relationship between pain and duration of diabetic foot ulcers was examined by using non-parametric testing with Spearman's rank correlation coefficient because of the not normal distribution. The duration of diabetic foot ulcers did not have any statistically significant correlation with the SF-MPQ scores between both settings.

Table 5. 36 Comparison of the short-form McGill pain questionnaire scores and duration of foot ulcer in Clinic S and Clinic P.

	Clinic S		**Clinic P**	
Variables	**Spearman's rank correlation coefficient p**	**p-value**	**Spearman's rank correlation coefficient p**	**p-value**
Duration of foot ulcer	0.04	0.647	0.169	0.060

5.8.2.3 Association between pain and co-morbidities conditions

The association between the SF-MPQ scores and co-morbidities were examined. Due to the not normal distribution, the Kruskal-Wallis test was used. The participants were divided into four groups according to to their number of health problems (Group 1: 1, Group 2: 2, Group 3: 0, Group 4: > 3).

In the Clinic S participants, there was a statistically significant difference in the SF-MPQ scores for the four groups (X^2= 8.13, p=0.043). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction revealed the significant difference in the SF-MPQ scores between one health problem and more than three health problems (z= - 2.69, p= 0.007).

Based on the median value scores, the participants who had more than three health problems besides diabetes obtained the highest median value on the SF-MPQ scores compared to the participants who had one health problem. Therefore, pain in the participants who had more than three health problems was more severe than in the participants who had only one health problem. However, there was no significant relationship between pain and co-morbidities for the Clinic P participants. The results are presented in Table 5.37.

Table 5. 37 Comparison of the short-form McGill pain questionnaire scores and number of other co-morbidities in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Number of other co-morbidities				8.13	0.043*				6.32	0.097
1	6.00	8.00	83.58			6.00	6.50	60.31		
2	6.00	7.00	84.68			7.50	9.50	68.11		
0	7.00	8.00	92.15			4.50	4.00	50.15		
≥3	15.00	12.50	125.58			10.00	19.00	78.82		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range * Indicated statistically significant result.

5.8.2.4 Association between pain and number of foot ulcer episodes

Table 5.38 showed that in order to determine whether the number of foot ulcer episodes in participants affected the SF-MPQ scores, the Kruskal-Wallis test was used (due to the not-normal distribution). The participants were divided into three groups according to the number of foot ulcer episodes (Group 1: 1st episode, Group 2: 2nd episode, Group 3: 3rd episode, Group 4: more than 3 episodes).

There was a statistically significant difference in the SF-MPQ scores for the four groups (X^2= 13.31, p= 0.004) in the Clinic S participants. The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction were used to identify significant differences between pairs of groups. There was a significant difference in the SF-MPQ scores between 1st episode of foot ulcer and 3rd episode of foot ulcer (z= -2.98, p= 0.003).

Based on the median value scores, the participants who were undergoing a 3rd episode of foot ulcer obtained the highest median value on the SF-MPQ scores compared to those who had experienced only the 1st episode. This indicated that participants who had experienced a 3rd episode of foot ulcer experienced more pain compared to those who were undergoing only the 1st episode of foot ulcer. However, there was no significant relationship between pain and the number of foot ulcer episodes for the Clinic P participants.

Table 5. 38 Comparison of the short-form McGill pain questionnaire scores and foot ulcer episode in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Foot ulcer episode				13.31	0.004*				3.21	0.361
1st episode	6.00	6.00	78.48			6.00	8.00	65.78		
2nd episode	8.00	11.50	97.78			6.00	5.50	55.86		
3rd episode	14.00	15.00	127.77			7.50	14.75	75.13		
More than 3 episodes	9.50	15.50	105.75			5.00	0	57.33		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range * Indicated statistically significant result.

5.8.2.5 Association between pain and site of foot ulcer

Table 5.39 presents the association between the SF-MPQ scores and the site of the foot ulcer. Due to the not-normal distribution, the Kruskal-Wallis test was used. The participants were divided into three groups according to the site of their foot ulcer (Group 1: midfoot, Group 2: forefoot, Group 3: hindfoot).

In the Clinic S participants, there was a statistically significant difference in the SF-MPQ scores for the three groups (X^2= 15.94, p<0.001). The Mann-Whitney U test and the post-hoc Bonferroni correction were also used in the post hoc analysis to identify significant differences between pairs of groups. The result revealed that there was a significant difference in the SF-MPQ scores between midfoot and forefoot (z= -3.98, p<0.001).

Based on the median value scores, the participants who had an ulcer at the forefoot obtained the highest median value on the SF-MPQ scores compared to at the midfoot, indicating that the pain was worse in participants who had a foot ulcer at the forefoot than those who had an ulcer at the midfoot. However, there was no significant relationship between pain and site of foot ulcer for the Clinic P participants.

Table 5. 39 Comparison of the short-form McGill pain questionnaire scores and site of foot ulcer in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Site of foot ulcer				15.94	<0.001*				0.56	0.758
Midfoot	6.00	4.00	75.05			6.00	7.00	64.89		
Forefoot	11.00	15.00	108.98			5.00	7.50	61.33		
Hindfoot	7.00	11.00	84.34			5.50	7.00	59.30		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range * Indicated statistically significant result.

5.8.2.6 Association between pain and severity of foot ulcer

Table 5.40 presents the association between the SF-MPQ scores and the severity of foot ulcer. Due to the not-normal distribution, the Kruskal-Wallis test was used. The participants were divided into four groups according to their wound classification (Group 1: Grade 1, Group 2: Grade 2, Group 3: Grade 3, Group 4: Grade 4).

There was a statistically significant difference in the SF-MPQ scores for the four groups in both sets of participants (X^2= 25.79, p <0.001; X^2= 17.00, p=0.001 respectively). In the Clinic S participants, the Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction revealed the significant difference in the SF-MPQ scores between Grade 1 and Grade 2 (z= -3.07, p= 0.002), Grade 1 and Grade 3 (z= -4.12, p<0.001), Grade 1 and Grade 4 (z= -3.29, p= 0.001) and Grade 2 and Grade 4 (z= -2.75, p= 0.006). In contrast, in the Clinic P participants, the Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction revealed the significant difference in the SF-MPQ scores between Grade 1 and Grade 3 (z= -4.12, p<0.001) and Grade 2 and Grade 3 (z= -3.21, p= 0.001).

Based on the median value scores, the participants from Clinic S who had a foot ulcer at Grade 4 in the Wagner wound classification obtained the highest median value on the SF-MPQ scores compared to those with Grade 1, Grade 2 and Grade 3, indicating that the pain was worse in participants who had a Grade 4 foot ulcer than in Grade 1, Grade 2 and Grade 3. In Clinic P, the participants who had a Grade 3 foot ulcer had more severe pain compared to those with Grade 1 and Grade 2 foot ulcers.

Table 5. 40 Comparison of the short-form McGill pain questionnairescores and severity of foot ulcer in Clinic S and Clinic P.

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Wagner wound classification				25.79	<0.001*				17.00	0.001*
Grade 1	5.00	3.00	62.10			5.00	4.50	55.78		
Grade 2	8.00	9.00	89.97			6.00	8.00	58.44		
Grade 3	9.00	14.00	105.77			12.50	11.00	94.75		
Grade 4	37.00	32.00	143.07			21.00	35.00	82.25		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range * Indicated statistically significant result.

5.8.2.7 Association between pain and frequency of dressing change

The association between the SF-MPQ scores and frequency of dressing change were examined. Due to the not-normal distribution, the Kruskal-Wallis test was used. The participants were divided into four groups according to their frequency of dressing change (Group 1: daily, Group 2: when needed, Group 3: once a week, Group 4: every alternate day).

In the Clinic S participants, there was a statistically significant difference in the SF-MPQ scores for the four groups (X^2= 18.03, p<0.001). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction revealed the significant difference in SF-MPQ scores between daily and every alternate day (z= -3.07, p=0.002), daily and once a week (z= -4.12, p<0.001), daily and when needed (z= -3.29, p=0.001), and every alternate day and when needed (z= -2.75, p=0.006).

Based on the median value scores, the participants who had a daily dressing change obtained the highest median value on the SF-MPQ scores compared to the participants who had their dressing changed every alternate day, when needed, and once a week. Therefore, pain in the participants who had a daily dressing change was more severe than in the participants who had their dressing changed every alternate day, when needed, and once a week (Table 5.41). However, there was no significant relationship between pain and frequency of dressing change for the Clinic P participants. This result suggests that frequency of dressing change does not have any effect on pain in this setting.

Table 5. 41 Comparison of the short-form McGill pain questionnairescores and frequency of dressing in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Frequency of dressing				18.03	<0.001*				3.20	0.362
Daily	20.00	26.75	130.40			6.00	7.00	63.28		
When needed	6.00	7.00	85.28			5.00	5.50	48.68		
Once a week	5.00	7.00	71.65			8.00	14.00	72.80		
Every alternate day	7.00	9.00	90.10			8.00	6.00	75.40		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range * Indicated statistically significant result.

5.8.2.8 Association between pain and type of cleaning solution

As the distribution was not normal, the Kruskal-Wallis test was used to determine the pain and how this was affected by the type of cleaning solution. The participants in both settings were divided into five groups according to their type of cleaning solution (Group 1: saline, Group 2: Dermacyn, Group 3: Hydrocyn, Group 4: Prontosan, Group 5: Sterile water).

There was a statistically significant difference in the SF-MPQ scores for the five groups in Clinic S and Clinic P (X^2= 12.61, p= 0.009; X^2= 9.73, p= 0.045 respectively). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction were used in the post hoc analysis to identify significant differences between pairs of groups. In the Clinic S participants, there was a significant difference in the SF-MPQ scores between Hydrocyn and sterile water (z= -3.13, p= 0.002) and Dermacyn and sterile water (z= -3.33, p= 0.001). However, there was no statistically significant difference between pairs of groups in the Clinic P participants

Based on the median value scores, the participants in Clinic S who used sterile water as a cleaning solution obtained the highest median value on the SF-MPQ scores compared to the participants who used Dermacyn and Hydrocyn. Therefore, pain in the participants who used sterile water as a cleaning solution was more severe than in the participants who used Dermacyn and Hydrocyn. The result is presented in Table 5.42.

Table 5. 42 Comparison of the short-form McGill pain questionnaire scores and type of cleaning solution in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Type of cleaning solution				12.61	0.009*				9.73	0.045*
Saline	8.00	14.00	91.62			5.50	7.00	61.21		
Dermaycyn	5.00	8.00	74.59			4.00	6.00	50.37		
Hydrocyn	6.00	6.00	83.69			6.00	6.00	63.53		
Prontosan	6.00	10.00	94.41			10.00	5.50	89.00		
Sterile water	15.50	21.75	131.92			28.00	0	109.33		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range * Indicated statistically significant result.

5.8.2.9 Association between pain and type of dressing

To determine whether the type of dressing affected the SF-MPQ scores, due to the not-normal distribution, the Kruskal-Wallis test was used. Participants in both settings were divided into five groups according to their type of dressing (Group 1: gel dressing, Group 2: dry gauze, Group 3: foam, Group 4: antimicrobials, Group 5: wet saline soaked dressing).

There was a statistically significant difference in the SF-MPQ scores for the five groups in participants in both clinics (X^2= 9.58, p= 0.048; X^2= 13.82, p= 0.008 respectively). The Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction were used in the post hoc analysis to identify significant differences between pairs of groups.

However, there was no statistically significant difference between pairs of groups in the Clinic S participants. In the Clinic P participants, there was a significant difference in the SF-MPQ scores between dry gauze and antimicrobial dressings (z= -3.06, p= 0.002) and dry gel and antimicrobial dressings (z= -3.37, p= 0.001).

Based on the median value scores, the participants in Clinic P who used antimicrobials for their dressing obtained the highest median value on the SF-MPQ scores compared to those who used gel and dry gauze. In summary, participants who used antimicrobials for their dressing experienced more pain compared with those participants who used gel and dry gauze. The result is presented in Table 5.43.

Table 5. 43 Comparison of the short-form McGill pain questionnaire scores and type of dressing in Clinic S and Clinic P

	Clinic S					Clinic P				
Variables	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**	**Median**	**IQR**	**Mean rank**	**Kruskal-Wallis X^2**	**p-value**
Type of dressing				9.58	0.048*				13.82	0.008*
Gel	6.00	7.00	84.14			5.00	6.00	59.86		
Dry gauze	10.50	19.50	107.00			5.50	6.50	55.10		
Foam	9.00	12.00	101.18			8.50	8.75	72.75		
Antimicrobials	23.00	0	157.50			27.00	26.00	106.93		
Wet saline soaked	14.00	0	112.83			11.50	0	90.25		

Note: X^2= Kruskal-Wallis test**,** IQR =Interquartile range * Indicated statistically significant result.

5.8.3 Comparison the association between pain and health-related quality of life

5.8.3.1 Association between pain and generic health-related quality of life

To determine whether there was a significant relationship between pain and generic health-related quality of life in both settings, the associations between the SF-MPQ scores and the SF-36 scales were examined using Spearman's rank correlation coefficient. Table 5.44 summarises the findings from the comparison between the SF-MPQ scores and SF-36 scales in both settings.

As a result, six SF-36 subscales had significant small-to-medium negative correlations with the SF-MPQ scores for participants from Clinic S. These subscales were Sf-36 role physical, bodily pain, vitality, social functioning, role emotional, and mental health (Spearman's rank correlation coefficient (p) range from -0.16 to -0.47, p values 0.032 to < 0.001). Thus, participants who experienced more pain had a reduced health-related quality of life in role physical, bodily pain, vitality, social functioning, role emotional, and mental health.

On the other hand, in Clinic P, five SF-36 subscales had significant small-to-medium negative correlations with the SF-MPQ scores; these subscales were Sf-36 bodily pain, vitality, social functioning, role emotional, and mental health (p range from -0.23 to -0.44, p values 0.010 to < 0.001). Thus, participants who experienced more pain had reduced health-related quality of life in bodily pain, vitality, social functioning, role emotional, and mental health.

Table 5. 44 Comparison of the short-form McGill pain questionnaire scores and the medical outcomes study 36- item short-form health survey in Clinic S and Clinic P.

	Clinic S		Clinic P	
Variables	**Spearman's rank correlation coefficient p**	**p-value**	**Spearman's rank correlation coefficient p**	**p-value**
SF-36				
Physical functioning	-0.08	0.300	-0.13	0.140
Physical role	-0.16	0.032*	-0.10	0.252
Bodily pain	-0.43	<0.001*	-0.34	<0.001*
General health	-0.12	0.10	-0.17	0.060
Vitality	-0.30	<0.001*	-0.40	<0.001*
Social functioning	-0.41	<0.001*	-0.23	0.010*
Emotional role	-0.41	<0.001*	-0.31	<0.001*
Mental health	-0.47	<0.001*	-0.31	<0.001*

* Indicated statistically significant result.

5.8.3.2 Association between pain and disease specific health-related quality of life

To determine the association between diabetic foot ulcer pain and disease specific health-related quality of life in the participants in both settings, the Spearman's rank correlation coefficient was used to estimate the correlation between SF-MPQ scores and DFS-SF.

However, all the subscales of DFS-SF had significant small-to-medium negative correlations with the SF-MPQ scores in both settings (Spearman's rank correlation coefficient (p) range from -0.17 to -0.52, p values 0.001 to < 0.001). Therefore, participants in both settings who were experiencing more pain had worse health-related quality of life in leisure, physical health, daily life, negative emotion, worried about ulcer and bothered by ulcer care. The result is presented in Table 5.45.

Table 5. 45 Comparison of the short-form McGill pain questionnaire scores and diabetic foot ulcers scale- short –form in Clinic S and Clinic P.

	Clinic S		Clinic P	
Variables	**Spearman's rank correlation coefficient p**	**p-value**	**Spearman's rank correlation coefficient p**	**p-value**
DFS-SF				
Leisure	-0.20	0.007*	-0.32	<0.001*
Physical health	-0.52	<0.001*	-0.37	<0.001*
Worried about ulcers/feet	-0.25	0.001*	-0.37	<0.001*
Dependence/ daily life	-0.17	0.028*	-0.34	<0.001*
Negative emotions	-0.47	<0.001*	-0.36	<0.001*
Bothered by ulcer care	-0.50	<0.001*	-0.41	<0.001*

* Indicated statistically significant result.

5.8.4 Comparison the association between pain and functional status

5.8.4.1 Association between pain and the Katz activity of daily living

To identify whether there were significant relationships between pain and independence in activities of daily living in both settings, the associations between the SF-MPQ scores and the Katz ADL were examined using Spearman's rank correlation coefficient; moderate negative correlations were demonstrated (Spearman's rank correlation coefficient (p)= -0.37, p< 0.001; p= -0.33, p< 0.001 respectively). In summary, participants in both settings who experienced more pain had a worse functional status. The result is presented in Table 5.46.

Table 5. 46 Comparison of the short-form McGill pain questionnaire scores and Katz index of independence in activities of daily living in Clinic S and Clinic P.

	Clinic S		**Clinic P**	
Variables	**Spearman's rank correlation coefficient p**	**p-value**	**Spearman's rank correlation coefficient p**	**p-value**
Katz activity of daily living	-0.37	<0.001*	-0.33	<0.001*

5.8.4.2 Association between pain and Lawton instrumental activity daily living

To determine whether there were significant differences between pain and instrumental ADL in both settings, the correlation was evaluated using Spearman's rank correlation coefficient. However, only mild negative correlations were reported (Spearman's rank correlation coefficient (p)= -0.22 p= 0.003; Spearman's rank correlation coefficient (p)= -0.18, p=0.046 respectively). Thus, participants from both settings experienced more pain and had reduced instrumental activities of daily living. The result is presented in Table 5.47.

Table 5. 47 Comparison of the short-form McGill pain questionnaire scores and Lawton instrumental activities of daily living in Clinic S and Clinic P.

	Clinic S		Clinic P	
Variables	**Spearman's rank correlation coefficient p**	**p-value**	**Spearman's rank correlation coefficient p**	**p-value**
Lawton instrumental activity daily living	-0.22	0.003*	-0.18	0.046*

5.9 Comparison the use of clinics between participants in Clinic S and Clinic P

5.9.1 Received information about wound pain control between participants in Clinic S and Clinic P

Regarding receiving verbal information, 90 (51.1%) of participants in Clinic S reported that they had not received the information on how to manage their pain, followed by 20.5% (n= 36) of participants, who had received some information and 14.8% (n= 26) of participants, who had received a lot of information, while 13.6% (n= 24) participants had received only a little information. A similar pattern was observed in Clinic P where most of the participants (n= 49, 39.5%) reported that they had not received the information on how to manage their pain, followed by 26.6% (n= 33) of participants, who had received some information, 25.0% (n= 31) of participants, who had

received a little information, and 8.9% (n= 11) of participants, who had received a lot of information

Related to receiving written information, 98 (55.7%) participants in Clinic S reported that they had not received any information on how to manage their pain, followed by 19.3% (n= 34) of participants, who had received some information and 14.8% (n= 26) of participants, who had received a little information, while 10.2 % (n= 18) of participants had received a lot of information. A similar pattern was observed in Clinic P, where most of the participants (n= 77, 62.1%) reported that they had not received any information on how to manage their pain, followed by 18.5% (n= 23) of participants, who had received a little information, 15.3% (n= 19) of participants, who had received some information, and 4.0% (n= 5) of participants, who had received a lot of information. Table 5.48 shows how much information the participants had received about wound pain control.

Table 5. 48 Received information about wound pain control between participants in Clinic S and Clinic P

	Clinic S		Clinic P	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
How much verbal information about wound pain control have you received?				
None	90	51.1	49	39.5
Some	36	20.5	33	26.6
A little	24	13.6	31	25.0
A lot	26	14.8	11	8.9
Total	**176**	**100.0**	**124**	**100.0**
How much written information about wound pain control have you received?				
None	98	55.7	77	62.1
Some	34	19.3	19	15.3
A little	26	14.8	23	18.5
A lot	18	10.2	5	4.0
Total	**176**	**100.0**	**124**	**100.0**

5.9.2 Provision of wound pain control between participants in Clinic S and Clinic P

When participants were asked who gave them the greatest quantity of information about wound pain control, the most commonly reported were the nurse (n= 63, 35.8%; n= 43, 34.7% in Clinic S and Clinic P respectively) followed by doctor (n= 16, 9.1 %) in Clinic S and (n= 10, 8.1%) in Clinic P. In Clinic S, five participants (2.8%) stated that they had received information from family or friends compared to nine participants (7.3%) in Clinic P. Only two (1.1%) of the participants in Clinic S and one participant (0.8%) in Clinic P had received information from the internet. In addition, participants also had received information from magazines (n= 1, 0.6% in Clinic S) and from other health care persons (n=1, 0.8% in Clinic P). However, 50.6% (n= 89) of participants in Clinic S and 37.1% (n= 46) in Clinic P reported that no one had provided them with information. Table 5.49 shows the provision of wound pain control in both clinics.

Table 5. 49 Provision of wound pain control between participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Whom have you received information from about wound pain control?				
No one	89	50.6	46	37.1
Nurse	63	35.8	43	34.7
Doctor	16	9.1	22	17.7
Family / friends	5	2.8	9	7.3
Internet	2	1.1	1	0.8
Magazine	1	0.6	0	0
Other health care person	0	0	1	0.8
Total	**176**	**100.0**	**124**	**100.0**

5.9.3 Satisfaction with wound care between participants in Clinic S and Clinic P

Table 5.50 indicates how satisfied the participants were with the care they had received regarding their wound. The majority of the participants in both clinics stated that they were satisfied with care they had received regarding their wound (n= 152, 86.4%: n= 95, 76.6% in Clinic S and Clinic P respectively). In addition, 9.1% (n= 16) of participants in Clinic S and 8.1% (n= 10) of participants in Clinic P were very satisfied with their wound care while eight participants (4.5%) in Clinic S stated that they were somewhat satisfied compared to 17 participants (13.7%) in Clinic P, with only two (1.6%) of the participants in Clinic P expressing dissatisfaction.

Table 5. 50 Satisfaction with wound care between participants in Clinic S and Clinic P

	Clinic S		**Clinic P**	
Variables	**Frequency**	**Percentage**	**Frequency**	**Percentage**
How satisfied have you been so far with the care of your wound has received in the health care clinic?				
Satisfied	152	86.4	95	76.6
Very satisfied	16	9.1	10	8.1
Somewhat satisfied	8	4.5	17	13.7
Dissatisfaction	0	0	2	1.6
Total	**176**	**100.0**	**124**	**100.0**

5.9.4 Comments and suggestion by Malaysian people over sixty years with diabetic foot ulcers to improve the quality of health services at Clinic S and Clinic P.

Comparisons were made of the themes and findings between Clinic S and Clinic P for the open-ended question. It was found that 260 comments did not address any specific theme but gave general positive feedback to the clinic: “good services”, “everything was excellent”, “nothing to complain about” and, “no suggestions”.

The seven themes that emerged from the analysis were staffing, the long waiting hours, follow-ups, the attitude of healthcare professionals, the poor wound assessment, the availability of up-to-date information, and the high cost of treatment.

As can be seen in Table 5.51, similar themes emerged from the open-ended question from participants in both clinics regarding staffing, the attitude of healthcare professionals, and the long waiting hours. Participants in both clinics suggested the need for more doctors and nurses and especially for wound care specialists. In both clinics, participants commented on the long waiting hours to receive a consultation with the doctors, medication, and treatment. In Clinic S, one participant commented that he had to wait too long for a scheduled follow-up.

As can be seen in the theme health care professionals, participants in both clinics perceived that health care professionals had a positive attitude by stating the nurses and doctors were helpful, very good, and polite. However, participants in both clinics had also had negative experiences with healthcare professionals’ attitude (see Table 4.52).

An important theme that emerged from the open-ended question in Clinic S was about the nurses’ skills in assessing the wound, as two participants commented on the nurses’ lack of skill in performing a wound assessment and how they failed to perform a wound assessment before dressing the wound.

Only Clinic P participants commented about the need to update information, such as the clinic’s activity and telephone number on the website. In addition,

one participant from Clinic P also was aware of the financial situation, as the cleaning solution for the wound dressing was expensive.

Table 5. 51 Themes that emerged from the open-ended questions in Clinic S and Clinic P.

Location	Themes
Clinic S	Staffing
	The attitude of health care professional
	The long waiting hours
	Follow-up
	The poor wound assessment
Clinic P	Staffing
	The attitude of health care professional
	The long waiting hours
	High cost of treatment.
	The availability of up-to-date information

Summary

This chapter has presented the results of the analyses of the relationship between pain and selected socio-demographic characteristics, selected clinical characteristics, health-related quality of life and functional status of people over sixty years with diabetic foot ulcers in Clinic S and Clinic P. In Clinic S, the duration of having diabetes mellitus, number of other comorbidities besides diabetes mellitus, number of foot ulcer episodes, site of foot ulcer, severity of foot ulcer, frequency of dressing change, type of cleaning solution, and type of dressing had a significant association with the SF-MPQ scores. However, after the Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction, there was no statistically significant difference between pairs of groups in type of dressing. This indicates that the people over sixty years with diabetic foot ulcers with a shorter duration of diabetes mellitus, having more than three health problems, having a 3rd episode of foot ulcer, having a foot ulcer at the forefoot, suffering from a Grade 4 foot ulcer, having a daily dressing change, and using sterile water as a type of cleaning solution were experiencing more pain. On the other hand, the significant values for Clinic P revealed that four variables had a significant association with the SF-MPQ scores (gender, severity of foot ulcer, type of cleaning solution, and type of dressing). However, after the Mann-Whitney U test and post hoc comparisons using the post-hoc Bonferroni correction, there was no statistically significant difference between pairs of groups in type of cleaning solution. This

indicates that patients who were female, suffering from a Grade 3 foot ulcer, and using an antimicrobial type of dressing experienced more pain.

In relation to the SF-36 in Clinic S, role physical, bodily pain, vitality, social functioning, role emotional, and mental health had a statistically negative association with the SF-MPQ scores. This indicates that the people over sixty years with diabetic foot ulcers who experienced more pain had reduced health-related quality of life in role physical, bodily pain, vitality, social functioning, role emotional, and mental health. The significant values for Clinic P revealed that five subscales of SF-36 had a significant association with the SF-MPQ scores; these subscales were bodily pain, vitality, social functioning, role emotional, and mental health. This indicates that the people over sixty years with diabetic foot ulcers who experienced more pain had reduced health-related quality of life in bodily pain, vitality, social functioning, role emotional, and mental health.

There are similarities regarding the DFS-SF, which showed there were significant differences in the distribution between Clinic S and Clinic P in this subscale. All subscales of DFS–SF had significant negative correlations with the SF-MPQ scores in both clinics. This indicates that in both clinics, the people over sixty years with diabetic foot ulcers, who were experiencing more pain, had worse health-related quality of life in leisure, physical health, and daily life, negative emotion, worried about ulcer and bothered by ulcer.

A similar pattern was observed regarding the Katz ADL and Lawton IADL. The results showed significant differences in the distribution between Clinic S and Clinic P in these scales. This indicates that in both clinics, the people over sixty years with diabetic foot ulcers, who were experiencing more pain, had a worse level of independence in functional status.

Analysis of the responses to the open-ended question revealed five themes or suggestions to improve the quality of health services at the clinic in Clinic S, such as staffing, the long waiting hours, follow-ups, the attitude of healthcare professionals, and the poor wound assessment, while in Clinic P, the themes that emerged were staffing, the long waiting hours, the attitude of healthcare professionals, the availability of up-to-date information, and the high cost of treatment. The discussion of the study is detailed in the next chapter.

CHAPTER 6

DISCUSSION

6.1 Introduction

As the number of people with diabetes mellitus is increasing rapidly, it is only natural that the number of patients with diabetic foot ulcers is also increasing, particularly among older people. Diabetic foot ulcers can result in pain, which has been reported to adversely affect health-related quality of life. However, research focusing on this issue is still very limited. The literature review highlighted the need to carry out such work to fill the research gap. Therefore, the current study has aimed to investigate the relationships between diabetic foot ulcer pain and health-related quality of life and functional status. The study was conducted among Malaysian people over sixty years with diabetic foot ulcers in Clinic S (secondary care clinic) and Clinic P (primary care clinic). This chapter will present the general findings of the study. Then, the data obtained from the sample of Malaysian people over sixty years with diabetic foot ulcers were separated according to the two clinics (Clinic S and Clinic P) in order to make a comparison between the two. The first section of this chapter discusses the participants' characteristics. Section two explores the findings from the SF-MPQ, the SF-36, the DFS-SF, the Katz ADL, and the Lawton IADL. Section three explores the associations between pain and the selected socio-demographic variables, selected clinical characteristics with the health-related quality of life, and the functional status of people over sixty years in Malaysia. This section also discusses the predictors of diabetic foot ulcer pain. Finally, section four discusses the way the people over sixty years with diabetic foot ulcers use health care clinics.

6.2 Characteristics of people over sixty years with diabetic foot ulcers

6.2.1 Socio-demographic characteristics

A total of 300 participants were recruited for the study. Among the 300 participants, 176 (49.7%) were from Clinic S (secondary care clinic) and 124

(50.3%) were from Clinic P (primary care clinic). Participants had a mean age of 65.19 (SD= 4.98) years. In the current study, most of the participants were aged less than 70 years old (82.3%). When compared to other studies, it has been found that patients with diabetic foot ulcers had a mean age of 60.8 (SD = 13.8) years in Ribu et al. (2006) and 67.5 (13.56) years in Bradbury and Price 2011a; Bradbury and Price 2011c (phase 1). Although these studies do not specifically focus on the older population with diabetic foot ulcers, they show a similar natural process of the condition, in which diabetic foot ulcers increase with age (Boultan et al. 2005). Therefore, in terms of age, these participants can be considered as being a good representation of older people with diabetic foot ulcers.

In the current study, there were more male patients (54.7%) than female patients (45.3%), which may indicate that foot ulcers are more common in males. This was in agreement with other studies involving patients with diabetic foot ulcers (Ribu et al. 2006; Bengtsson et al. 2008; Bradbury and Price 2011a; Bradbury and Price 2011c (phase 1); Mazlina et al. 2011; Yunus and Rajbhandari 2011; Obilor and Adejumo 2014). This could be associated with the fact that men can be less conscientious about foot care and participate in more activities compared to women (Nwabudike and Ionescu 2008). Thus, in the light of previous findings, it was not surprising that a higher proportion of males attended both Clinic S and Clinic P during the data collection, and it is reasonable to assume the sample in the current study reflects the situation throughout the country.

Participants in the current study identified with different ethnic groups reflective of the multi-ethnicity and cultural diversity of Malaysia (Department of Statistics Malaysia 2010). The population comprises 60% Malays, 23% Chinese, and 7% Indians while the rest of the population comprises other smaller ethnic groups in East and West Malaysia plus a small population of aborigines (Department of Statistics Malaysia 2010). In the current study, the sample comprised 47% Malays, 27% Indians, 24.7% Chinese, and 1.3% of other ethnicities. The high proportion of Indians compared to Chinese in the current study was expected since patients of Indian ethnicity tend to have a higher risk of developing diabetes (Ministry of Health Malaysia 2013; Wan Nazaimoon et al. 2013). In addition, both clinics are situated in a predominantly Malay population area.

Therefore, this sample is representative of people over sixty years with diabetic foot ulcers in terms of racial status.

Regarding religion, a majority of the participants in the current study were Muslims (47%), followed by Hindus (24.3%), Buddhists (24.3%) and those of other religions (3.4%). This finding is consistent with the 2010 National Census of the religious composition of the population in Malaysia (Department of Statistics Malaysia 2010). In terms of religion, the sample is representative of people over sixty years with diabetic foot ulcers in Malaysia.

Most participants in the current study were married (72.3%), close to twenty-five percent (23.4%) were either widowed, divorced or separated, while a small number of participants (4.3%) were single, which is very similar to the data from the Department of Statistics Malaysia (2010). Therefore, this sample is representative of people over sixty years with diabetic foot ulcers in terms of marital status.

The people over sixty years in the current study were born more than half a decade ago, that is, before Malaysia gained independence in 1957. Therefore, they were expected to have had less opportunity to receive a formal education. This is because before Malaysia gained independence, most of the Malay families traditionally lived in a kampong or village located in rural areas while the schools were typically built in urban centres, and most of the time, were inaccessible to the Malay population (Nooraini and Khairul Azmi 2011). The findings from the 2000 Population Census showed that 51% of older people had received no formal education (Rabieyah and Hajar 2003). However, over the last few decades, an emerging trend shows that older people in Malaysia are becoming more educated. According to Tengku Aizan (2012), the proportion of people aged 60 years and above who have never been to school decreased from 73.2% in 1980 to 51.3% in 2000. In the current study, the proportion of the participants who had received a secondary and tertiary education was 60.6%, indicating that participants in the current study were generally more educated. It was expected that educated Malaysian older people with diabetic foot ulcers would be better informed about their illness and might have better coping skills. Moreover, older people's understanding of health information depends on their level of education. Normah et al. (2014) stated that older people with a lower

education level have a relatively poor understanding of health education, and this has resulted in an unsatisfactory health status compared to those with a higher level of education (Shahar et al. 2012).

A majority of the participants in the current study lived in homes with additional floors (1½ floors, 2 floorss, 2 ½ floors and 3 floors and above) (59.7%) compared to those homes without additional floors (40.3%). This could be because the study was conducted in an urban area rather than in a rural area. Therefore, this environmental factor might contribute to the greater incidence of diabetic foot ulcer pain that could possibly be due to patients putting more stress on their feet when climbing stairs. Education on foot care, and particularly on pain management, should be introduced to patients who live in homes with more than one floor as the risk of having diabetic foot ulcer pain is relatively higher compared to patients who live in homes only one floor.

6.2.2 Clinical characteristics

In the current study, the participants had been diagnosed as having diabetes mellitus for a median of 18.5 years (range 0.25 to 35 years). The distribution of having diabetes mellitus was not normal, but for comparison with other studies, the mean score 17.5 years (SD= 8.5) was used. The duration of having diabetes mellitus was considerably shorter than in other studies. Ribu et al. (2006) reported a mean duration of diabetes mellitus of 19 years in Norwegian patients. In addition, Bradbury and Price (2011a) and Bradbury and Price (2011c) [phase 1] reported a mean duration of diabetes mellitus of 18.8 years in British patients. A possible reason for the shorter time range could be because the participants in the current study were not aware of their condition at the time of diagnosis, thus allowing complications such as diabetic foot ulcers to occur. This explanation is supported by the Malaysia National Health Morbidity Survey (NHMS) (2011) highlighting that 52% of those with diabetes who were above the age of 18 years old were unaware of their diagnosis.

Nearly half of the participants (49.7%) were on insulin therapy, and this was a bigger percentage than those reported in previous study at the Malaysian primary care clinic (21.4%) (Ministry of Health Malaysia 2012b). This finding was similar to a cross-sectional study which was conducted by Ribu et al.

(2006). The authors reported that 70% of the participants with diabetic foot ulcers were treated with insulin while 30% of the participants were taking oral hypoglycaemic agents and were on dietary treatment only. There was a possibility that insulin therapy was prescribed because of a poor metabolic control, meaning the patient had a high fasting plasma sugar and glycated haemoglobin (HbA1c). In Malaysia, patients are prescribed insulin after they have been on a maximum number of oral hypoglycaemia and have failed to achieve the glycaemic target (Azidah et al. 2014). This could suggest that that the participants in the current study had not been successful in controlling their sugar level and so required insulin therapy. However, the levels of fasting plasma sugar and HbA1c of the patients were not asked for in the current study. In a study by Sazlina et al. (2015), which assessed the control of glycaemia and other cardiovascular disease risk factors among older adults with type 2 diabetes in Malaysia, it was found that the proportion of Malaysians aged ≥ 60 years with glycated haemoglobin (HbA1c) level ≥ 7.0% was 58.3%. A national study was conducted in the United States (Margaret et al. 2009) in order to estimate the prevalence, awareness, pharmacologic treatment, and control of hypertension, dyslipidaemia, and diabetes among adults aged 65 years and older. The authors reported that 50.4% of the older population had good blood glucose control (based on the level of glycated haemoglobin (HbA1c) of lower than 7%) compared to the Malaysian older population. It would seem that Malaysian older people have a poor glycaemic control compared to their counterparts in western countries, meaning they are at a higher risk of diabetic complications.

Nearly half of the participants in the current study (44%) reported having at least one additional health problem. In the current study, the researcher identified only the number of co-morbidities present at the time of assessment, and the information on the type of health problems was based on the self-report method. However, several participants identified their health problems to the researcher, which included renal problems, hypertension, and heart diseases. The current study findings are consistent with those of previous studies, which found that medical comorbidities, such as hypertension, ischemic heart disease, and renal disease, are the most common comorbidities of diabetic foot ulcer patients (Mazlina et al. 2011; Zakaria et al. 2015). For example, Mazlina et al.

(2011) conducted a comparative study of the health-related quality of life of patients with diabetic foot disease compared to patients without diabetic foot disease. They found hypertension, ischemic heart disease, and renal disease to be the most common co-existing chronic diseases in an adult population with diabetic foot disease in Malaysia. These findings suggest that the current study is representative of diabetic foot ulcer patients in Malaysia, and the most common comorbidities are hypertension and heart disease.

More than half of the participants (57.3%) in the current study reported that this was the first time that they had a foot ulcer. This finding was similar to a Taiwanese study by Hui et al. (2008). In their study, the majority of the participants reported having a foot ulcer for the first time.

In the current study, the participants had been diagnosed as having diabetic foot ulcers for a median of three months (range 1 to 96 months). The time from the participants being first diagnosed was considerably longer than in other studies. For example, a study by Ribu et al. (2006) reported a median ulcer duration of two months (range 0 to 144 months) for adults with a current diabetic foot ulcer. A possible reason for the longer median of the time from diagnosis could be because the participants in the current study were older individuals compared to the samples in previous studies.

In the existing literature, the site of diabetic foot ulcers varied, as was the case with the participants in the current study. In a study by Apelgvist et al. (1990), the site of the foot ulcer area was found at the toes (dorsal and plantar surface) (51%); metatarsal heads, midfoot and heel (28%); and dorsum of the foot (14%); while some had multiple ulcers (7%). In a study in Norway by Ribu et al. (2006), the site of the foot ulcer was reported at the toe (46%), metatarsal (20%), midfoot/hindfoot (17%) and multiple locations (18%). The most common sites for diabetic foot ulcers were the toes followed by the metatarsal. On the other hand, the findings of the current study have indicated that most diabetic foot ulcers occurred at the midfoot (47.3%), forefoot (31.3%), and the hindfoot (21.3%). The site of foot ulcers in the study by Apelgvist et al. (1990) and Ribu et al. (2007) were partially similar to the current study; however, the multiple ulcers in both studies may explain the differences. Multiple ulcers were not examined in the current study, and this may be considered as one of the

limitations of the current study. Therefore, further research should be carried out to investigate the relationship between diabetic foot ulcer pain and ulcers at multiple sites.

In the current study, injury (61%) was found to be the most commonly reported perceived cause of diabetic foot ulcers. Self-reports from participants indicated that the causes of injury were mostly from nail or glass paring and callus removal. This finding was similar to a study by Obilor and Adejumo (2014). In their study, the main cause of diabetic foot ulcers was injury. This finding contradicts the study by Huang et al. (2012) where a majority of the participants believed that the cause of their foot ulcer was improperly fitting footwear (19.8%). The possible explanations as to why injury was a common cause for diabetic foot ulcers could be due to the participants in the current study being older individuals who had higher risks of injury.

The severity of diabetic foot ulcers was classified using the Wagner wound classification system (Wagner 1981) as recommended in clinical practice guidelines on the management of diabetic foot ulcers (Ministry of Health Malaysia 2004). In the current study, the most common stage of diabetic foot ulcers was grade 2 (39.3%), which is consistent with the Malaysian study by Mazlina et al. (2011), in which the majority of the participants also had grade 2 ulcers (60.6%). In the study by Ribu et al. (2006), it was reported that 58% of the participants had a grade 1 diabetic foot ulcer. A possible reason for a majority of older people in Malaysia having a severe diabetic foot ulcer compared to those in previous studies could be late presentation to the hospital and delayed treatment (Rampal et al. 2010).

Dressing changes in the current study were carried out on a daily basis (40.7%) using normal saline (33.7%) as the cleansing agent. In Malaysia, the selection of cleansing agent was made in accordance with the clinical practice guidelines on the management of diabetic foot ulcers (Ministry of Health Malaysia 2004). This was in agreement with the findings in the study by Obilor and Adejumo (2014), where a majority of the participants had their dressing changed on a daily basis (n=13) with normal saline as the cleansing solution.

In the current study, modern wound dressings were used for most participants in treating diabetic foot ulcers, such as gel and antimicrobial dressings (78%

and 3.3% respectively) while the use of gauze and wet saline soaked dressings seem to be decreasing in popularity (12% and 1.7% respectively). This is in contrast with the study by Obilor and Adejumo (2014), where a majority of their participants used plain gauze and honey as a dressing material.

In the current study, over half of the participants (52.7%) were not taking analgesics, while 47.3% of the participants who had taken an analgesic reported that they perceived it to be effective in relieving their pain. This is contrary to the findings of the study by Bradbury and Price (2011a) and Bradbury and Price 2011c (phase 1), which indicated that a slightly higher percentage (57%) of the participants who reported diabetic foot ulcer pain were taking analgesics compared to those who were not taking any.

Overall, most participants in the current study were male, aged between 60-69 years, married, of Malay ethnicity, Muslim, with a secondary level of education and living in homes with multiple floors. Compared to other studies, the duration for which the participants had been diagnosed with diabetes mellitus was shorter, while the duration from the time the patients were diagnosed with a foot ulcer was longer. Most participants had at least one additional health problem, had an ulcer at the midfoot, with injury being the main cause of the diabetic foot ulcer. Participants were suffering from an ulcer which according to the Wagner wound classification was grade 2, had a daily dressing change, and used a gel dressing as well as normal saline as a dressing and cleansing agent. Participants in the current study were selected from a Clinic S and a Clinic P. Both Clinic S and Clinic P provide treatments for all patients with diabetic foot ulcers in Malaysia. In conclusion, the researcher argues that the study sample represents people over sixty years with diabetic foot ulcers in Malaysia in terms of their socio-demographic and medical characteristics.

6.3 Pain experience of people over sixty years with diabetic foot ulcers in Malaysia

The first objective of the current study, as stated at the beginning of Chapter 1, was to measure the pain experienced by people over sixty years with diabetic foot ulcers in Malaysia.

Chronic pain is a very uncomfortable and distressing condition. There has been growing evidence to suggest that diabetic foot ulcers can be associated with pain. Thus, it is important to understand the relationships between diabetic foot ulcers and the associated pain on patients' health-related quality of life as well as their functional status. The stage of diabetic foot ulcers is significant here because it is believed that chronic wound pain is related to deeper and consequently more severe wounds (Quirino et al. 2003), such as Grade 3 and Grade 4 diabetic foot ulcers. Diabetic foot ulcer pain arises from tissue damage or from the dysfunction of the nervous system. There are two main types of pain, namely, nociceptive and neuropathic. This classification has been identified in a number of previous studies (Wulf and Baron 2002).

The pain experience in the current study was explored using the SF-MPQ (Melzack 1987) (see Chapter 3). Its components include sensory dimension, affective dimension, VAS, and PPI. Scores of the sensory dimension and affective dimension are summed to provide a pain experience score in which a higher score represents greater pain.

In the current study, diabetic foot ulcer pain was experienced by all the people over sixty years (n=300). The results of pain in the current study specifically support the findings by Ribu et al. (2006), Bengtsson et al. (2008), Yunus and Rajbhandari (2011), Bradbury and Price (2011a), Bradbury and Price (2011b), Bradbury and Price (2011c), and Obilor and Adejumo (2014), all of which highlighted that diabetic foot ulcer pain is a problem. This is in contrast with previous opinions, which suggested that the incidence of pain among those with diabetic foot ulcers is rare due to the sensation loss associated with peripheral neuropathy, unless accompanied by infection or Charcot foot (Gordois et al. 2003; Sibbald et al. 2003).

There is no prior research on the diabetic foot ulcer pain of people over sixty years in Malaysia to compare with the findings of the current study. Only one study (Bradbury and Price 2011a; Bradbury and Price 2011c [phase 1]) was found that used the same measurement tools as the current study, namely, the SF-MPQ. The authors reported that 86% of the participants had reported some degree of pain. However, in Bradbury and Price's study, each foot ulcer was categorized based on its aetiology: neuropathic, ischaemic, or neuroischaemic,

or other causes known to cause pain in diabetic foot ulcers such as infection, Charcot foot, or osteomyelitis, while in the current study, no categorization of foot ulcer was made, which might explain the inconsistency in the results. As it is important to determine if patients can distinguish pain based on the aetiology of their diabetic foot ulcer, this may be considered as one of the limitations of the current study. Therefore, further research should be carried out to investigate the pain experience based on the aetiology of diabetic foot ulcers. The different findings between the current study and those by Bradbury and Price (2011a) as well as Bradbury and Price 2011c [phase 1] also could be explained in terms of the methodology adopted in the latter two studies whereby the sample size (n= 28) was relatively small and participants were recruited from a local specialist foot clinic, while participants in the current study were recruited from a referral hospital and a community centre in Malaysia.

A number of other studies that used different measurement tools also found that pain is associated with diabetic foot ulcers. Ribu et al. (2006) investigated 127 Norwegian individuals with diabetic foot ulcers. Occurrence of pain was assessed using two items from the DFS (i.e., pain while walking and/or standing and pain during the night related to foot ulcer problems). The result revealed that 75% of the participants reported pain related to diabetic foot ulcers; of the 75%, 57% reported diabetic foot ulcer pain while walking and/or standing and at night time. A similar finding on pain was reported by Bengtsson et al. (2008), who used the 10 mm VAS; in their study, it was also shown that 53% of the 101 patients reported wound-related pain either intermittently or continuously. Yunus and Rajbhandari (2011), on the other hand, used the s-LANSS (Bennett et al. 2005) for their study. They reported that 43.2% of the participants with diabetic foot ulcers had signs and symptoms of painful neuropathy. In a recent study of 14 patients with diabetic foot ulcers in Nigeria, Obilor and Adejumo (2014) used the VAS for diabetic foot ulcer pain assessment, and the finding indicated that all the participants (n=14) experienced diabetic foot ulcer pain at rest and while performing daily living activities. In addition, it was reported in a number of qualitative studies that people with diabetic foot ulcers experienced pain (Ashford et al. 2000; Ribu and Wahl 2004; Bradbury and Price 2011b; Bradbury and Price 2011c [Phase 2]). Ashford et al. (2008) used semi-structured interviews in which twenty-one patients shared individual

experiences of living with diabetic foot ulcers. Pain was the dominant aspect of living for people with diabetic foot ulcers. Ribu and Wahl (2004) used in-depth interviews with seven patients to derive the themes of living with a diabetic foot ulcer, with incessant pain being one of the six themes. In the study by Bradbury and Price (2011b) as well as Bradbury and Price (2011c [Phase 2]), three participants described their diabetic foot ulcer experience, and pain emerged as a theme. Although the sample sizes were generally small in the qualitative studies, pain can be considered a critical theme.

The other main purpose within this section is to compare the pain intensity experienced by patients between the two clinics. In doing that, it was found that patients in Clinic S had a higher score in the SF-MPQ compared to those in Clinic P. This shows that people over sixty years old with diabetic foot ulcers in Clinic S are more likely to report a higher pain experience compared to those in Clinic P. This is probably due to the severe diabetic foot ulcer conditions and numerous chronic illnesses that triggered the pain among the patients in Clinic S, which is hospital based compared to Clinic P, which is community based. Furthermore, Clinic S is a referral centre for all of Malaysia; therefore, it receives more patients with complications and provides a relatively better representation of the general population.

6.3.2 Components of the short-form McGill pain questionnaire

In the current study, the VAS, characteristics of pain, and PPI were the three components that made up the SF-MPQ.

The VAS (0-100 mm) in the short form McGill pain questionnaire was used to assess the people over sixty years's pain intensity in the current study. The people over sixty years were asked to mark with an "X" on the line to indicate their pain at that time. In the current study, the median score was 35.4 (IQR= 29.7). The mean VAS score was affected by skewness; however, for the purpose of comparing the results with other studies, the mean score 39.4 (SD= 19.94) was used. The VAS score in the current study was considerably higher than that of other studies. The mean VAS score in a study by Bradbury and Price (2011a) as well as Bradbury and Price 2011c (phase 1) was 26.4 (SD= 24.3). The reasons for getting different rates of pain intensity may be the

cultural differences and the population being studied. Comparing the results between the two clinics, it was evident that the patients in Clinic S tended to have a more intense pain experience compared to those in Clinic P.

The SF-MPQ was also used in the current study to elicit the characteristics of diabetic foot ulcer pain. The various terms used by the patients to describe their diabetic foot ulcer pain are similar to what is described by patients with chronic wounds (World Union of Wound Healing Societies (WUWHS) 2004; Bradbury and Price 2011a; Bradbury and Price 2011c [phase 1]). The common choice of words such as throbbing, tender, aching, gnawing, shooting, stabbing, and sharp as well as hot burning indicated that diabetic foot ulcer pain in the current study may involve both nociceptive and the neuropathic pain. A similar finding on characteristics of diabetic foot ulcer pain was also reported by Bengtsson et al. (2008) as well as by Obilor and Adejumo (2014). For example, Obilor and Adejumo (2014) reported that the participants in their study described diabetic foot ulcer pain as stinging, tingling throbbing, and aching. In the United Kingdom, in Bengtsson et al.'s (2008) study, the participants used terms such as burning, pricking, stinging, sore, and pulsating/gripping to describe the nature of their pain experience. When comparing the characteristics of pain experienced by patients in both clinics, similarity between the two was found with throbbing, tender, aching, gnawing, shooting, stabbing, sharp, and hot burning the common choice of words.

The PPI in the SF-MPQ describes the pain that patients feel at the time of answering the questions. There are five descriptors of pain listed in the form ranging from no pain (0) to excruciating (5). While it appears there has been no study examining the PPI, this comparison has been explored in other studies of chronic wounds. The PPI reported by patients in the current study is consistent with the wound-related research conducted on leg ulcer pain, such as a study by Hopman et al. (2013), who reported that 157 of the 564 patients had mild pain. When comparing the PPI in both clinics, it was shown that the results were comparable, as a majority of them reported having mild pain.

In summary, to the researcher's knowledge, this is the first study to report on the level of diabetic foot ulcer pain in Malaysia. Therefore, it can only be compared with studies undertaken outside Malaysia. However, the findings

agreed with those from previous studies. The comparisons were complex in nature due to the differences between the measurement tools or the population being studied. It is worth noting that in the current study, the participants were recruited from a hospital-based clinic (Clinic S) and a community health clinic (Clinic P) with a larger sample size (n=300) compared to those from previous studies. This large sample size should give a relatively better representation of the general population of Malaysian people over sixty years with diabetic foot ulcers. When making comparisons between both clinics, the patients with diabetic foot ulcers from Clinic S were more likely to report greater pain compared to patients from Clinic P due the severe diabetic foot ulcer conditions as well as the numerous chronic illnesses that trigger pain among people over sixty years with diabetic foot ulcers in Clinic S. At the time this thesis was being written, it was the first study to compare the pain intensity experienced by patients in a secondary care clinic with that experienced by those in a primary care clinic, within either in a Malaysian or a Western context. Therefore, the results are unique, and there is no similar study to compare them with.

6.4 Health-related quality of life of people over sixty years with diabetic foot ulcers in Malaysia

The second objective of the current study was to measure the health-related quality of life of people over sixty years with diabetic foot ulcers in Malaysia.

Diabetes is a serious disease and has significant effects on quality of life. This is evident in a number of studies in which diabetes has been shown to have a negative impact on the health-related quality of life, particularly in the presence of complications (Goodridge et al. 2005; Ahola et al. 2010; Darvishpoor and Abed 2013; Basir et al. 2016). A study which was conducted in Tehran on a heterogeneous sample of adults with diabetes, using a generic health-related quality of life instrument (the SF-36 survey) has shown that older persons reported more impairment in their physical as well as social function, and less impairment in mental health as compared to younger diabetic persons. Similar findings were reported in a study by Kamarul Imran et al. (2010), who conducted a cross-sectional study in Malaysia to compare the quality of life based on the SF-36 between two different groups of type 2 diabetes mellitus patients with glycaemic control: those with a glycosylated haemoglobin (HbA1c)

level at or below 7.5 percent and those above 7.5 percent. Based on the results obtained through the SF-36, type 2 diabetes mellitus patients with poor glycaemic control has lower mean in physical functioning, general health, social functioning and mental health as compared to good glycaemic control (Kamarul Imran et al. 2010). Therefore, identifying strategies to improve health-related quality of life among patients with diabetes mellitus is of great importance.

6.4.1 The medical outcomes study 36- item short-form health survey

A number of studies on people with diabetic foot ulcers have shown that they experience a reduced health-related quality of life (Meijer et al. 2001; Willrich et al. 2005; Evans and Pinzur 2005; Nabuurs-Franssen et al. 2005; Goodridge et al. 2006; Boutoille et al. 2008); Winkley et al. 2009; Jelsness-Jorgensen et al. 2011; de Meneses et al. 2011; Morales et al. 2011; Sanjari et al. 2011; Huang et al. 2012). In the current study, the generic health-related quality of life was assessed using the medical outcome survey short-form 36 (SF-36) (Ware and Sherbourne 1992). The SF-36 has comprehensive physical and mental dimensions, with eight subscales for physical function, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. Higher scale scores indicate a better quality of life.

The findings of the current study have shown that the physical component summary in people over sixty years with diabetic foot ulcers in Malaysia is lower than the norm (cut-off score 50). On the other hand, the mental health component summary was higher than the norm of 50 (Table 6.3). This suggests that people over sixty years with diabetic foot ulcers in the current study experience more deterioration of their physical health compared to their mental health. In terms of the subscale of the SF-36 in the current study which looked at physical functioning, role physical and general health, the score was lower than the norm of 50, indicating that people over sixty years with diabetic foot ulcers have an impaired physical functioning, role physical, and general health. Only in the SF-36 bodily pain section was the score higher than the norm of 50.

The current study also revealed that the health-related quality of life for people over sixty years with diabetic foot ulcer in Malaysia is relatively low for most domains of the SF-36 compared to the general older population of Malaysia

(Sararaks et al. 2005), as shown in Table 6.1. This suggests that patients with diabetic foot ulcers in the current study have poor physical, mental, and social health status. The normal scores for the physical component summary and mental health component summary were not available for the general Malaysian population; therefore, comparisons were made only for the eight SF-36 domains.

When compared with the general diabetes population, the current study have found that people over the age of sixty with diabetic foot ulcer reported lower SF-36 scores in most domains in comparison to the diabetes population in Malaysia (Basir et al. 2016), as shown in Table 6.1. Similar findings were reported in the study by Ribu et al. (2007), who conducted a cross-sectional study among 127 adults with current diabetic foot ulcers by comparing their health-related quality of life with that of a sample from the general population without diabetes (n = 5,903) and a subgroup with diabetes but without foot ulcers (n = 221) to examine the differences between groups by socio-demographic characteristics and lifestyle factors. In all the SF-36 domains and in the two SF-36 summary scales, patients with diabetic foot ulcers reported significantly lower health-related quality of life compared to the population with diabetes mellitus but without diabetic foot ulcers (Ribu et al. 2007).

Table 6. 1 Comparison of medical outcomes study 36- item short-form health survey subscales between current study and Malaysian people over sixty years population.

SF-36 subscales	The current study Mean (SD)	Clinic S Mean (SD)	Clinic P Mean (SD)	General population (Saravaks et al. 2005) Mean (SD)	Diabetes population (Basir et. al. 2016) Mean (SD)
SF-36 Physical health summary	**45.98 (14.24)**	**45.55 (14.60)**	**46.58 (13.74)**	**-**	**-**
Physical functioning	33.88 (22.43)	32.27 (22.58)	36.16 (22.11)	69.78 (23.55)	46.58 (15.52)
Role physical	49.77 (20.73)	49.91 (21.95)	49.58 (18.93)	67.59 (41.69)	48.58 (26.59)
Bodily pain	57.68 (20.61)	57.45 (21.34)	58.00 (19.62)	63.23 (20.20)	61.77 (15.15)
General health	42.58 (12.73)	42.58 (13.80)	42.57 (11.08)	55.81 (22.90)	46.63 (12.37)
SF-36 Mental health summary	**59.94 (14.02)**	**60.10 (14.04)**	**59.71 (14.03)**	-	-
Vitality	51.25 (13.76)	51.10 (13.91)	51.45 (13.59)	60.59 (19,90)	59.71 (14.26)
Social functioning	58. 46 (20.93)	58.90 (21.52)	57.84 (20.12)	78.41 (23.96)	61.05 (17.35)
Emotional role	66.77 (25.58)	66.25 (25.51)	67.51 (25.77)	77.08 (38.05)	81.16 (20.46)
Mental health	63.26 (13.91)	64.13 (14.73)	62.03 (12.62)	73.25 (18.38)	63.50 (10.75)

SF-36: The medical outcomes study 36- item short-form health survey

The only study that examined the relationships between foot problems and health-related quality of life in patients with diabetes in Malaysia was carried out by Mazlina et al. (2011). The SF-36 questionnaire was used to assess the health-related quality of life in 140 diabetic patients with foot problems attending an outpatient diabetic foot clinic in a tertiary hospital in Malaysia, as shown in Table 6.2. The median was used for comparisons due the non-normality of the SF-36 data from the study by Mazlina et al. (2011). It was found that all the subscales (physical function, role physical, body pain, general health, vitality, social functioning, emotional role, and mental health) were lower than that of Mazlina's study, indicating that health-related quality of life is worse in the current study. Although both studies were conducted in Malaysia, they involved two different populations; the current study focused on people over sixty years with diabetic foot ulcers, while the study by Mazlina et al. (2011) was carried out on the general population suffering from different types of foot disease specifically foot ulcers, symptomatic foot neuropathy, symptomatic peripheral arterial disease, or active Charcot arthropathy, and the participants were

recruited from a specialised diabetic foot clinic in one centre. This may explain the different findings.

Several studies have investigated the health-related quality of life for patients with diabetic foot ulcers (Meijer et al. 2001; Willrich et al. 2005; Evans and Pinzur 2005; Nabuurs-Franssen et al. 2005; Goodridge et al. 2006; Boutoille et al. 2008); Winkley et al. 2009; Jelsness-Jorgensen et al. 2011; de Meneses et al. 2011; Morales et al. 2011; Sanjari et al. 2011; Huang et al. 2012). For example, Meijer et al. (2011) conducted a study on 14 patients with a previous or current diabetic foot ulcer and a comparison was made with 24 controls without ulcers, matched for age, sex, and duration of diabetes. The study reported that existing or previous foot ulcer episodes had a negative influence on the physical and social aspects of the participants' health-related quality of life. Although the study sample size was small and the participants were located within different populations and settings, the findings were similar and suggest that limitations on physical functioning as well as mobility can reduce the self-reported health-related quality of life.

When comparing the generic health-related quality of life for patients in both clinics, as was expected, the study findings show that the physical and mental health summary scores of the generic SF-36 in participants for Clinic S and Clinic P were below the norm (cut-off score 50) except for the mental health summary scores in Clinic S. Furthermore, the summary scores for the physical health domain in Clinic S were lower than those of Clinic P (see Table 6.1). This suggests that people over sixty years with diabetic foot ulcers in Clinic S may have experienced more deterioration in the physical health domains as compared to their mental health domains. This result may be explained by the fact that Clinic S is hospital based, so it is very likely that there are more patients with diabetes mellitus or diabetic foot ulcer complications, and a more difficult metabolic control and treatment than was expected in people over sixty years having their follow-ups with general practitioners in Clinic P. However, the patients in Clinic P had poorer mental health summary scores compared to those in Clinic S, which indicated that patients in Clinic P were having difficulties in performing their daily roles due to emotional problems. However, there was no clear reason for this. Therefore, strategies need to be implemented which include an early detection and proper management of these psychological

disturbances for older patients and their families to ensure that there is a proper metabolic control, that a good quality of life is maintained, and that the patients will have better treatment adherence.

In terms of the subscales of the SF-36, it was shown that the results were comparable for people over sixty years with diabetic foot ulcers in both clinics where physical functioning, role physical, and general health scores were lower than the norm of 50.

Table 6. 2 Comparison of medical outcomes study 36- item short-form health survey subscales between current study and Mazlina et al. (2011) study

SF-36 subscales	The current study Medium (IQR)	Clinic S Medium (IQR)	Clinic P Medium (IQR)	Mazlina et al. (2011) Medium (IQR)
Physical functioning	30.00 (35.00)	27.50 (38.75)	30.00 (30.00)	55.00 (40.00)
Role physical	50.00 (32.50)	50.00 (37.19)	50.00 (29.69)	68.75 (43.75)
Bodily pain	55.00 (22.50)	55.00 (25.00)	55.00 (22.50)	54.0 (41.00)
General health	40.00 (10.00)	40.00 (10.00)	40.00 (10.00)	53.12 (43.75)
Vitality	50.00 (15.00)	50.00 (15.00)	50.00 (10.00)	55.00 (40.00)
Social functioning	50.00 (25.00)	50.00 (25.00)	50.00 (25.00)	68.75 (50.00)
Emotional role	75.00 (50.00)	75.00 (50.00)	75.00 (50.00)	83.33 (50.00)
Mental health	64.00 (20.00)	64.00 (20.00)	60.00 (20.00)	65.00 (50.00)

SF-36: The medical outcomes study 36- item short-form health survey

6.4.2 The diabetic foot ulcer scale-short form

On the other hand, disease specific health-related quality of life in the current study was assessed using the DFS-SF (Bann et al. 2003). The DFS-SF has five subscales to measure different domains of quality of life, such as leisure, physical health, daily activities, emotions, and treatment. Higher scale scores indicate a better quality of life.

To date, at least to the researcher's best knowledge, this is the first study in Malaysia to report on health-related quality of life using the DFS-SF. The results revealed that diabetic foot ulcers have negative relationships with health-related quality of life. The current study is similar to that of Hui et al. (2008) in the sense that the assessments were done using similar tools. To translate the DFS-SF into Chinese and evaluate psychometric performance, Hui et al. (2008) examined the health-related quality of life in 60 patients with diabetic foot ulcers. The current study has shown that the mean values of the DFS-SF subscales had lower scores in four subscales (leisure, physical health,

dependence/daily life and worried about ulcers/feet) compared to the mean values of Hui et al.'s (2008) study. The subscale of being bothered by ulcer care and negative emotions was slightly higher in the current study as compared to Hui et al.'s (2008) study as shown in Table 6. 3. The differences in the above findings could be related to several factors. Firstly, the cultural aspects, such as belief, ethnicity, and religion are found to reflect a person's perceived health-related quality of life (Saxena et al. 2002). For example, Alzahrani and Sehlo (2011) found a relationship between religious connectedness and health-related quality of life in their study on diabetic foot ulcer patients in Saudi Arabia. Secondly, the level of social and family support received by participants varies from one country to another depending on the strength of the family relationship; however, this was not explored in the current study.

When comparing the disease specific health-related quality of life in both clinics, the study findings show that the participants in Clinic S had lower scores in leisure and physical health compared to participants in Clinic P, indicating that people over sixty years in Clinic S were more likely to have difficulties socializing or participating in leisure activities and to have impaired physical health.

In contrast, the study findings show that the subscales of being worried about ulcers/feet as well as the feeling of being bothered by ulcer care were higher for patients in Clinic S compared to those in Clinic P. Within the subscales of having the feeling of being bothered by ulcer care, patients were asked whether they were bothered by treatment-related instructions, the appearance of the ulcer, and dependence on others to take care of their foot ulcer (Bann et al. 2003). The patients in Clinic S seemed to have not been affected severely by these issues compared to those in Clinic P. Patients with diabetic foot ulcers in Clinic P had a lower score for the subscale of worrying about ulcers/feet compared to those in Clinic S. However, there was no clear reason for this. One possible explanation is the presence of odour and exudate in patients with ulcers resulting in a bad body image (Parker 2012), which would subsequently lead to patients worrying.

Table 6. 3 Comparison of the diabetic foot ulcer scale short-form subscales between current study and Hui et al. (2008) study

DFS-SF subscales	The current study Mean (SD)	Clinic S Mean (SD)	Clinic P Mean (SD)	Hui et al. (2008) Mean (SD)
Leisure	50.00 (45.00)	47.50 (35.00)	50.00 (50.00)	54.25 (33.33)
Physical health	55.00 (25.00)	55.00 (30.00)	60.00 (20.00)	69.92 (25.80)
Dependence/ daily life	55.00 (35.00)	55.00 (40.00)	55.00 (30.00)	71.42 (32.85)
Negative emotions	75.00 (41.6)	75.00 (40.63)	75.00 (41.67)	74.58 (28.92)
Worried about ulcers/feet	28.84 (37.5)	30.77(45.19)	23.08 (34.62)	59.69 (35.16)
Bothered by ulcer care	75.00 (43.7)	75.00 (43.75)	68.75 (42.19)	71.04 (28.49)

DFS-SF: The diabetic foot ulcers scale-short form

In summary, there were similarities and differences in the health-related quality of life between the current study and the previous studies. In general, tients with diabetic foot ulcers have a significantly poor health-related quality of life. When comparing the results between both clinics, it was found that patients in Clinic S had reduced health-related quality scores particularly in the physical health summary compared to those in Clinic P. At the time this thesis was being written, this was the first study to compare health-related quality of life of patients in a secondary care clinic with those in a primary care clinic, within either a Malaysian or Western context. Therefore, the results are unique, and there is no similar study to compare them with.

6.5 Functional status of people over sixty years with diabetic foot ulcers in Malaysia

The third objective of the current study was to measure the functional status of people over sixty years with diabetic foot ulcers in Malaysia.

Diabetes mellitus is a leading cause of disability among adults and often results in many limitations in functional status (Al Snih et al. 2005). Cross-sectional studies (Gregg et al. 2000; Peter et al. 2001) and longitudinal studies (Voplpato et al 2002; Gregg et al. 2002) have been carried out to examine the effect of diabetes mellitus on incident functional disability. These studies have found diabetes mellitus to be associated with an increased incidence of functional disability. For instance, Gregg et al. (2002) have assessed incident function disability in older non-Hispanic women with diabetes mellitus and the results have shown that risk of disability is related to increasing age, cardiovascular

heart disease, severe visual impairment, and depressive symptomatology. Patients with type 2 diabetes mellitus have been identified to suffer impaired physical health-related quality of life (Basir et al. 2016). For instance, physical functioning domain has been indicated to be the most affected for patients having diabetes mellitus linked with physical difficulties; consequently hampering the daily activities and work abilities of those patients. Therefore, identifying strategies to improve functional status among patients with diabetes mellitus is of great importance.

6.5.1 The Katz index of independence in activities of daily living and Lawton instrumental activities of daily living

At the time this thesis was being written, there were no studies found that used the Katz ADL and the Lawton IADL either in the Malaysian or in Western populations with diabetic foot ulcers. The Katz ADL was designed to measure physical functioning, such as bathing, dressing, transferring, toileting, continence, and feeding. On the other hand, the Lawton IADL was designed to measure a higher level of physical functioning than the index of ADL, such as travelling, shopping, preparing meals, housework, and managing medications, the telephone, and money. In the current study, the Katz ADL and the Lawton IADL were selected because the questionnaire was a well-validated measurement tool used in older populations.

It is not surprising that the majority of patients in the current study did not present problems with functional status in both the Katz ADL and the Lawton IADL. The median score total was Katz ADL 6 (IQR= 0) and Lawton IADL 7 (2). This suggests that people over sixty years with diabetic foot ulcers could carry out each self-care activity independently and perform each IADL independently. The current study was conducted in an urban setting, and the majority of the participants were between the age range of 60-69 years (young-old age), meaning 82.3% were still in the productive age group. This may be the reason why Malaysian people over sixty years with diabetic foot ulcers were found to be independent in performing ADL and IADL.

When comparing the functional status in both clinics, it was shown that the results were comparable for both clinics for people over sixty years with diabetic

foot ulcers where majority of them were able to carry out each self-care activity independently and perform each IADL independently.

While it appears there has been limited research examining the association between functional status and pain among diabetic foot ulcer patients using the Katz ADL and the Lawton IADL, specifically in Malaysia, this relationship has been explored in other different measurement tools. For example, Meijer et al. (2006) investigated the quality of life of patients with current or former diabetic foot ulcers by making a comparison with diabetes mellitus patients without foot ulcers. The ADL was assessed with the Barthel Index (Mahoney and Barthel 1965). The Barthel Index consists of 10 questions on skills/disabilities in performing ADL. The maximum score is 20 points (normal), and less than 10 points means severely impaired ADL. They found that the study group (with foot ulcer) scored 19.2 points, and the control group (without foot ulcer) scored 19.8 points, indicating the participants in the study were able to perform self-care ADL independently.

In summary, the findings on functional status in the current study revealed that people over sixty years with diabetic foot ulcers in the current study did not have problems in performing self-care activities and IADL independently. Similar findings were also reported when making comparisons between both clinics. No study was found that provided the same measurement tools that could be used for comparison. Further research is needed to explore functional status among the patients with diabetic foot ulcers using Katz ADL and Lawton IADL in Malaysia. When comparing the results between both clinics, it was found that patients in Clinic S and Clinic P were able to carry out each self-care and IADL activity independently. At the time this thesis was being written, it was the first study to compare generic health-related quality of life for patients in a secondary care clinic with those in a primary care clinic, within either a Malaysian or the Western contexts. Therefore, the results are unique, and there is no similar study to compare them with.

6.6 Association between pain and the selected socio-demographic variables, selected clinical characteristics, health-related quality of life and functional status of people over sixty years in Malaysia

The fourth objective of the current study was to explore the significant factors related to diabetic foot ulcer pain.

6.6.1 Association between pain and the selected socio-demographic variables

6.6.1.1 Age categories

Age is another factor that relates to how patients experience pain. Increasing age has been found to be significantly associated with pain. However, the findings of the current study do not support the previous research. In the current study, the age of the participants was not significantly associated with diabetic foot ulcer pain. There was no statistically significant difference at $p<0.05$ level in the SF-MPQ. This result suggests that age does not have an effect on diabetic foot ulcer pain. This finding was consistent with that of Ribu et al. (2006), who found that age was not significantly associated with diabetic foot ulcer pain.

A possible explanation for this might be that older patients are reluctant to report pain (Miaskowski 2000). This is because they may believe that pain is normal and is an inevitable part of getting older or being chronically ill (Thielke et al. 2012). Some older people may not report pain because they fear that pain is a sign of their worsening illness or even impending death (Herr and Garand 2001). This assumption is supported by the findings in a study by Daousi et al. (2004). In their study on 35 diabetic patients in the United Kingdom, it was found that 12.5% of patients with peripheral diabetic pain never reported their symptoms to physicians (Daousi et al. 2004).

When comparing the results between both clinics, it was found that pain was not statistically associated with age categories for patients in both Clinic S and Clinic P. The result suggests that age categories do not have an effect on diabetic foot ulcer pain in both clinics.

6.6.1.2 Gender

Most epidemiological studies have indicated that women have a significantly higher prevalence of pain compared to men (Bartley and Fillingam 2013). In the current study, it was found that gender was significantly associated with diabetic foot ulcer pain. Older females with diabetic foot ulcers were more likely to report a higher intensity of pain compared to their male counterparts. This finding, however, was inconsistent with the study carried out by Ribu et al. (2006), in which it was found that gender was not significantly associated with diabetic foot ulcer pain.

The higher scores in older females with diabetic foot ulcers most probably reflect the attitudes of female patients, who are more aware of their health condition and of ways to manage it. This simply means that the women were more conscious of their health, and as a result, they were generally more willing to report pain compared to the male patients. Previous research in Malaysia conducted by Ho et al. (2014) found that older women with diabetes were significantly more likely to be aware of their condition than were men. Therefore, more effort should be focused on ways to increase the awareness about diabetic foot ulcer pain among older men in order to ensure that early treatment is sought and to prevent complications.

Cultural factors also provided an explanation for the different ways chronic pain is expressed between men and women (Bartley and Fillingam 2013). In many cultures, females are found to have the tendency to express their feelings more explicitly compared to their male counterparts (Yu et al. 2006). It was the researcher's observation that the men in Malaysia felt obliged to give the impression of being strong and so were not supposed to express their feelings of pain. It was perceived that it is a cultural norm among men, that they are required to be physically and emotionally stronger and braver than women to be able to protect the women. On the hand, women are brought up to be emotionally expressive and highly dependent on men.

Another possibility of this is the fact that, at present, most of the older persons in Malaysia play a crucial role as supporters for their families, such as by cooking, cleaning, taking care of their grandchildren, and looking after the house, and in some cases, by providing financial support. It has been accepted

in Malaysian culture that the woman is the heart of the house, and thus women are expected to perform the household chores even when they are not in the best of health. As these chores require a lot of movement, there is a tendency for women to experience more pain compared to men.

When comparing the results for patients in both clinics, it was found that gender was not significantly associated with diabetic foot ulcer pain in Clinic S. There was no significant difference in the SF-MPQ. This result suggests that gender in Clinic S does not have an effect on diabetic foot ulcer pain. In contrast, older females with diabetic foot ulcers in Clinic P were more likely to report intense pain compared to male patients.

6.6.1.3 Race and religion

In the current study, it was found that the participants' race and religion were not significantly associated with diabetic foot ulcer pain. This result suggests that race and ethnicity do not have an effect on diabetic foot ulcer pain. Therefore, this finding does not support previous research that has suggested that ethnicity and religion are two factors that strongly influence the expression of pain (Chan et al. 2011). To date, there has been no known published research that has investigated the relationship between diabetic foot ulcer pain with ethnicity and religion. To the best of the researcher's knowledge, this is the first study to examine the association of race and religion with diabetic foot ulcer pain. Therefore, it was difficult to compare these findings with findings from other studies. Further research is therefore needed to explore the relationship between pain and ethnicity and ethnicity and religion in Malaysia.

The relationship between pain and ethnicity and religion among older people with other chronic diseases has been examined in previous studies. One example was a study conducted by Dunn (2005) in which 200 Judeo-Christians (Catholic, Protestant or Jewish) elderly people were recruited. It was found that pain intensities were not related to any cultural or racial background. However, it is important to note that as the study focused only on Judeo Christians, then the findings have a limited ability to be generalized to a wider population.

A possible explanation for this was the fact that the current study was conducted in an Asian cultural setting. According to Chen et al. (2011), Asian

patients are more reluctant to report on the pain that they are experiencing and may be less assertive compared to Western patients. Similarly, reporting pain may be considered an act of complaining; therefore, an Asian patient may prefer not to report the pain in order that doctors or nurses will perceive them to be “a good patient” (Wong and Chan 2009).

Furthermore, a majority of the participants in the current study were Muslims (47%). It is strongly believed among Muslims that pain and suffering caused by illness are regarded as a test of faith in God to determine a person’s level of patience. They believe a person who has a high level of patience will be closer to God. Additionally, Islam teaches that pain and suffering will delete the sins.

Another possible explanation for this was that the distribution of participants in each ethnic group was not large and therefore the Chinese, and the Indians as well as people of other ethnic groups were under-represented. Therefore, the comparisons made between groups have contributed to the absence of statistical differences.

When comparing the results between both clinics, it was found that race and ethnicity were not significantly associated with diabetic foot ulcer pain in either Clinic S or Clinic P. This result suggests that race and ethnicity do not have an effect on diabetic foot ulcer pain for patients in both clinics.

6.6.1.4 Marital status

In the current study, it was found that pain was significantly associated with a patient’s marital status. Compared to other groups, people over sixty years with diabetic foot ulcers who were married had a higher tendency to experience an intense pain. The results came as a surprise, as it had been presumed that patients who were married would have strong support from their spouse and children.

It is a practice in Malaysian culture that the elderly live with and are taken care of by their immediate family members, particularly their spouse and children. This is a notion that is strongly promoted in all the ethnic groups in the country. However, currently, the family structure is undergoing changes that may be attributed to urbanization (Ambigga et al. 2011), which has also resulted in

changes in societal values. This, in turn, may cause elderly people to lose the support that they once had. Another possible explanation for this is the inconvenience that comes with wound care, and this includes the treatment needed, the frequency of changing their dressing, and their dependence on others. Therefore, married people over sixty years have a higher tendency to experience pain with a high intensity. For example, in the subscales of the feeling of being bothered by ulcer care in the DFS-SF, there was a negative significant correlation with diabetic foot ulcer pain, indicating that people over sixty years who claimed that they were bothered by ulcer care were more likely to have a higher pain intensity.

When comparing the results for patients between the two clinics, marital status was found to be not significantly associated with diabetic foot ulcer pain in both Clinic S and Clinic P. This result suggests that marital status does not have an effect on diabetic foot ulcer pain in Clinic S and Clinic P.

6.6.1.5 Educational level

In the current study, it was found that pain was not significantly associated with patients' educational level. This result suggests that educational level does not have an effect on diabetic foot ulcer pain. This was consistent with the results from a previous study by Ribu et al. (2006), which found that level of education did not have a significant effect on diabetic foot ulcer pain.

It is interesting to note, however, that although the educational level was not related to diabetic foot ulcer pain, the result is clinically important because it showed that as education level decreased, the scores of the SF-MPQ increased. It can be deduced that participants in the current study may be at risk of experiencing a higher intensity of pain because of their background of low educational level. The reason may be that older people with lower educational levels have difficulty in remembering or understanding all the information about pain management or diabetic foot ulcer care, which consequently leads to uncontrolled pain.

On the other hand, older people with high educational levels have a better ability to obtain information. In this study, they were more aware of the resources available and knew how to use these resources to relieve as well as

manage their pain. It was only natural that educated patients would have a better access to all the information about their illness, and hence, the knowledge could help them to cope with their condition better.

Therefore, it is recommended that older people with diabetic foot ulcers be regularly assessed for their pain. The numeric rating scale and VAS can be used as a screening tool in order to identify older people who are in pain. Older people who are found to be in pain should be referred to chronic pain specialists for further treatment.

When comparing between both clinics, on the level of education of people over sixty years with diabetic foot ulcers, it was found that it was not significantly associated with diabetic foot ulcer pain. This result suggests that level of education does not have an effect on diabetic foot ulcer pain in both Clinic S and Clinic P.

6.6.1.6 Number of floors in the patient's home

As mentioned in section 6.2.1, the environmental factors such as the number of floors in a patient's home might contribute to a greater incidence of diabetic foot ulcer pain. However, in the current study, it has been discovered that pain was not significantly associated with the number of floors in a patient's home. There was no significant difference in the SF-MPQ scores. This result suggests that the number of floors in a patient's home does not have an effect on diabetic foot ulcer pain.

The association between diabetic foot ulcer pain and the number of floors in a patient's home has not been previously reported in the literature. To the best of the researcher's knowledge, this is the first study to have examined whether the number of floors in a patient's home is associated with diabetic foot ulcer pain. Therefore, it was difficult to compare these findings with other studies. Further research is needed to explore the relationships between pain and the number of floors in the patient's home in Malaysia.

The reason behind this could be the possibility that most diabetic patients in Malaysia live with family members, which is preferable to living alone. Family members can provide the patient with the psychological, social, and physical

support that they need. However, living arrangements were not one of the factors examined in the current study, which may be considered as one of the limitations of the current study. Therefore, further research should be carried out to investigate the relationships between living arrangements and diabetic foot ulcer pain.

When comparing the results between both clinics, it was found that pain was not significantly associated with the number of floors in a patient's home for patients in both clinics. This result suggests that the number of floors in the patient's home does not have an effect on diabetic foot ulcer pain in either Clinic S or Clinic P.

In summary, the current study found that diabetic foot ulcer pain was higher in people over sixty years in Malaysia who were female and married. A limited amount of literature was found on the association between diabetic foot ulcer pain and the socio-demographic variables. Nevertheless, the study by Ribu et al. (2006) was the only one that examined the association between diabetic foot ulcer pain and socio-demographic variables. However, none of the socio-demographic variables (age, gender, cohabitation, education, and employment) was found to be associated with diabetic foot ulcer pain. This could be because the sample size in Ribu at al. (2006), which was split into three groups – those who experienced pain none of the time, a little or some of the time, and most or all of the time - was relatively small. Therefore, there was a decreased likelihood of detecting a statistical relationship between the socio-demographic variables and diabetic foot ulcer pain.

When comparing the relationships between pain and socio-demographic variables for patients in both clinics, one variable was found to be significantly associated with pain: older females with diabetic foot ulcers in Clinic P had a greater tendency to experience a more intense pain compared to their male counterparts. At the time this thesis was being written, this was the first study to compare pain and socio-demographic characteristics in a secondary care clinic with those in a primary care clinic, within either in Malaysian or Western contexts. Therefore, the results are unique, and there is no similar study to compare them with. Future studies on the relationship between diabetic foot ulcer pain and the socio-demographic variables are therefore recommended.

6.6.2 Association between pain and the selected clinical characteristics

6.6.2.1 Duration of having diabetes mellitus

In the current study, it was found that pain was not significantly associated with the duration of a patient's diabetes. There was no significant correlation between the total scores of the SF-MPQ and the duration of a patient's diabetes mellitus of. This result suggests that the duration of diabetes mellitus does not have an effect on diabetic foot ulcer pain. The finding was consistent with those of Ribu et al. (2006), which showed that the duration of diabetes mellitus was not associated with diabetic foot ulcer pain.

A comparison was made between both clinics of the relationships between pain and the duration of diabetes mellitus; a negative correlation was generated from the scores of the SF-MPQ with the duration of diabetes mellitus for patients in Clinic S. However, that was not the case for patients with diabetes in Clinic P. The result suggests that people over sixty years with a shorter duration of diabetes mellitus in Clinic S were more likely to report higher levels of pain. However, there was no clear reason for this. Further research is needed to explore the relationship between pain and the duration of diabetes mellitus in Malaysia.

6.6.2.2 Number of co-morbidities

From the study conducted, it was found that pain was significantly associated with the number of co-morbidities of a patient. People over sixty years with diabetic foot ulcers who were diagnosed with more than three health problems were more likely to report a higher intensity of pain. It had been highly expected that comorbidity would increase the pain intensity in diabetic foot ulcer patients. Comorbidities, particularly kidney failure, hypertension, and heart problems, are commonly found in patients with diabetic foot ulcers. While a diabetic foot ulcer itself can result in pain, another chronic illness will make the pain even worse.

This concurs with a previous finding of a study on 1,592 community-dwelling older adults with chronic pain (Onubogu 2014) that a higher number of comorbidities was significantly correlated with more severe bodily pain. Similarly,

in a study by Caporali et al. (2005), which included 29,132 participants with chronic pain, it was reported that pain was significantly worse ($p<0.0001$) when patients had two or more comorbidities. However, the findings of the current study were inconsistent with a study conducted in Norway by Ribu et al. (2006) in which it was found that the number of co-morbidities was not associated with diabetic foot ulcer pain.

The relationship between pain and the number of co-morbidities for patients in both clinics was compared. For Clinic S, it was found that patients with more than three co-morbidities were more likely to experience intense pain. However, for patients in Clinic P, a contrasting result was found where there was no significant association between the two. This result suggests that the number of co-morbidities did not have an effect on diabetic foot ulcer pain for patients in Clinic P.

6.6.2.3 Duration of foot ulcer

In investigating the relationship between the duration of foot ulcer episodes and pain in the current study, it was found that pain was not significantly associated with the duration of the patient's foot ulcer episode. There was no significant correlation with the total scores of the SF-MPQ and the duration of foot ulcer episodes. This result suggests that the length of time a patient suffers from foot ulcers does not have any effect on diabetic foot ulcer pain. This finding was consistent with that of Ribu et al. (2006), who conducted a similar study in Norway.

When comparing the relationships between pain and the duration of the patients' foot ulcers in both clinics, it was found that there was no statistically significant association in the duration of foot ulcer episodes with the total scores for both clinics. This result suggests that the length of time a patient suffers from foot ulcers does not have any effect on diabetic foot ulcer pain in both clinics.

6.6.2.4 Episode of foot ulcer

In the current study, it was found that pain was significantly associated with the number of episodes of foot ulcers in a patient. People over sixty years who were

reported to be experiencing the 3rd episode of foot ulcers were more likely to have intense pain compared to others with fewer episodes of foot ulcers. Patients with a 3rd episode of diabetic foot ulcers may experience more intense pain due to the impacts from past experience, such as painful dressing changes. A similar thought was expressed in the study by Mudge et al. (2008), where a patient's perception of pain may be influenced by a negative experience, which has developed into memories of wound-related pain.

A comparison was made of the relationship between pain and the number of foot ulcer episodes for patients in both clinics. It was found that in Clinic P, the number of foot ulcer episodes was not significantly associated with diabetic ulcer pain. This result suggests that the number of foot ulcer episodes does not have an effect on diabetic foot ulcer pain. On the contrary, the patients in Clinic S, who were experiencing a 3rd episode of diabetic foot ulcers had a tendency to experience an intense pain compared to others with fewer foot ulcer episodes.

The association between pain and the number of foot ulcer episodes has not been previously reported in the literature. Therefore, it was difficult to compare these findings with other studies. Further research is needed to explore the relationships between pain and the number of foot ulcer episodes in Malaysia.

6.6.2.5 Site of foot ulcer

The site of the foot ulcer was another related factor of diabetic foot ulcer pain that was being investigated in the current study. It is commonly known that pain is significantly associated with the site of a foot ulcer. People over sixty years with a foot ulcer at the forefoot were more likely to report a higher intensity of pain compared to those whose foot ulcer was sited at other places, such as the hindfoot or the midfoot. However, there was no clear reason for this. One possible explanation was that it may be due to excessive pressure at the forefoot area while walking or standing. Similar findings were evident in earlier studies, in which standing and walking even short distances were found to give increased pain, as reported by Ribu et al. (2006) and Bengstoon et al. (2008) as well as in qualitative studies by Ashford et al. (2000), Ribu and Wahl (2004), Bradbury and Price (2011b) and Bradbury and Price (2011c (phase 2)).

However, the findings of the current study are inconsistent with a study in Norway by Ribu et al. (2006), where the authors found that the site of the foot ulcer was not associated with diabetic foot ulcer pain.

A comparison was made of the relationship between pain and the site of the foot ulcer for patients in both clinics. It was found that patients in Clinic S who were suffering from foot ulcers at the forefoot had a higher tendency to report intense pain compared to those who had a foot ulcer at different sites, such as the hindfoot or the midfoot. In contrast, the site of the foot ulcer was not significantly associated with diabetic foot ulcer pain for patients in Clinic P. This result suggests that the site of the foot ulcer did not have an effect on diabetic foot ulcer pain for patients in Clinic P.

6.6.2.6 Severity of foot ulcer

It is well known that the intensity of the pain is significantly associated with the severity of the foot ulcer. In the current study, people over sixty years with a Grade 4 foot ulcer were more likely to report a higher pain intensity compared to those suffering from other grades of foot ulcer. In contrast, Bengtsson et al. (2008) conducted a pilot study on 101 patients with diabetic foot ulcers. Using a similar wound classification, those patients with Grade 1 and Grade 2 diabetic foot ulcers presented a higher score in both clinics. However, this result needs to be interpreted with certain considerations due to the fact that the current study only included patients suffering from Grade 1 and Grade 2 diabetic foot ulcers.

In contrast, in a study conducted in Norway, Ribu et al. (2006), using similar wound classifications, reported that there was no significant difference between the severity of the foot ulcer and diabetic foot ulcer pain.

Though it appears that there have been only a limited number of studies examining the association between the severity of diabetic foot ulcers and pain among diabetic foot ulcer patients, this comparison has been explored with regard to other chronic wounds. This finding is consistent with prior research in pressure ulcer pain (Dallam et al. 1995; Szor and Bourguignon et al. 1999; Langemo et al. 2000; Quirino et al. 2003; Ülkü 2008). Research by Langemo et al. (2000) and Quirino et al. (2003) found that patients suffering from stage IV

ulcers have higher scores of pain. Similarly, Ülkü (2008) reported that perceived pain intensity was highest in patients with stage IV ulcers, corresponding to 'horrible' pain. This trend also was also observed by Dallam et al. (1995) as well as by Szor and Bourguignon et al. (1999), who found that patients with stage IV ulcers tended to report more severe pain compared to those suffering from a lower stage of pressure ulcers. Therefore, the result suggests that patients with a higher stage or grade of wound ulcer are more likely to report a higher pain intensity compared to those with a superficial stage or grade of wound ulcer.

A comparison was made of the relationship between pain and the severity of the foot ulcer for patients in both clinics, and it was found that patients with a Grade 4 foot ulcer in Clinic S were more likely to report a more intense pain compared to those suffering from other grades of foot ulcer within the same clinic. Meanwhile, in Clinic P, patients with a Grade 3 foot ulcer were more likely to report a higher pain intensity compared to those suffering from other grades of foot ulcer.

6.6.2.7 Frequency of dressing change

Research has shown that chronic wound patients have described pain as being most intense during dressing change (Price et al. 2008). However, pain was not significantly associated with frequency of dressing change in the current study. This finding contradicts the finding from a study by Bengtsson et al. (2008); they investigated whether patients with neuropathic or neuroischaemic ulcers experience painful sensations. Of the 53 patients, it was found that 19 (36%) of the patients experienced pain during dressing change. Furthermore, as mentioned by Upton et al. (2013) in a study comparing pain experience in patients with diabetic foot ulcers with the perceptions of clinicians, the result showed that 48% of the participants reported having experienced a moderate to severe pain due to dressing change. In addition, findings from a qualitative study have also provided a description of patients' pain experience during dressing change. Pain was the encompassing theme that emerged in the phenomenological study after interviews with 21 patients suffering from diabetic foot ulcers. These participants reported experiencing pain during dressing change (Ashford et al. 2000). Similarly, studies by Bradbury and Price (2011b)

as well as (Bradbury and Price 2011c [phase 2]) have also shown that people in their study with diabetic foot ulcers experienced pain due to dressing change.

A comparison was made of the relationship between pain and the frequency of dressing change for patients in both clinics, and it was found that the frequency of dressing change was not significantly associated with diabetic foot ulcer pain in Clinic P, and this contrasts with the finding in Clinic S. The current study suggests that people over sixty years with diabetic foot ulcers in Clinic S and who were on daily dressing change were more likely to report an intense pain.

It was not possible to perform a more in-depth comparison in the frequency of dressing change because there were no other studies that provided details of the frequency of dressing change. Further research is needed to explore the relationships between pain and frequency of dressing change in Malaysia.

6.6.2.8 Type of cleaning solution

Previous studies have shown that a wound cleansing solution is very likely to evoke pain during dressing change (Hollinworth and Collier 2000; Moffatt et al. 2002). Pain was significantly associated with the type of cleaning solution used in the current study. The results of the current study suggest that patients who were treated with sterile water were more likely to report an intense pain. The findings of the current study are consistent with a study in Nigeria which was carried out on 14 patients with diabetic foot ulcers. The VAS was used for diabetic foot ulcer pain assessment, and the finding indicated that 71.4% of the participants reported the experience of having mild to severe pain during wound cleansing using normal saline (Obilor and Adejumo 2014).

A comparison was made of the relationship between pain and the type of cleaning solution for patients in both clinics. It was found that pain was significantly associated with the type of cleaning solution in Clinic S. Patients in Clinic S who were treated with sterile water were more likely to report an intense pain. In contrast, pain was not significantly associated with the type of cleaning solution in Clinic P. This result suggests that the type of cleaning solution does not have an effect on diabetic foot ulcer pain in Clinic P for people over sixty years with diabetic foot ulcers.

6.6.2.9 Type of dressing.

In the current study, it was found that pain was significantly associated with the type of dressing. The current study suggests that people over sixty years with diabetic foot ulcers who used antimicrobial dressings were more likely to report having an intense pain. The same finding was demonstrated in a cross-sectional international study (Price et al. 2008), as 14% of the study participants reported the experience of having severe pain due to the use of an antimicrobial dressing.

However, a different finding was reported in the United Kingdom. In a case series study (Bradbury et al. (2011), 26 patients (venous leg ulcer=11, surgical wound=3, pressure ulcer=4, diabetic foot ulcer=6) were treated with Silvercel Non-Adherent dressings for a duration of nine weeks (range 3–20 weeks). A majority of the patients reported having no or a decreased wound pain after the treatment was completed. Therefore, the Silvercel Non-Adherent dressings were found to be effective in managing wound-related pain for various wound types. Similarly, Sibbald et al. (2011) found that pain was significantly reduced with antimicrobial dressings. Based on these findings, there seems to be a discrepancy in the results between the current study and the previous study regarding the association between the type of wound dressing and diabetic foot ulcer pain. Therefore, further research is needed to investigate this relationships in the Malaysian context.

On the other hand, in a study in which plain gauze and honey were used as the dressing agent, Obilor and Adejumo (2014) reported that 71.4% of the participants reported experiencing mild to severe pain during the application of the dressing agent.

A comparison was made of the relationship between pain and the type of dressing for patients in both clinics, and it was found that the notion of pain being significantly associated with the type of dressing was evident in Clinic P. Patients with diabetic foot ulcers who were treated using antimicrobial dressings in Clinic P were more likely to report having an intense pain. In contrast, the results obtained have shown that pain was not significantly associated with the type of dressing in Clinic S. This suggests that the type of dressing does not

have an effect on diabetic foot ulcer pain in Clinic S for people over sixty years with diabetic foot ulcers.

In summary, through the current study, it was found that diabetic foot ulcer pain was more likely to be experienced by people with more than 3 health problems; having a 3rd episode of foot ulcers, which in most cases are on the forefoot; suffering from a Grade 3 or Grade 4 foot ulcer; having a daily dressing change; and using sterile water and antimicrobials for wound treatment. As with the socio-demographic variables, there was limited literature on the association between diabetic foot ulcer pain and the clinical variables. There was only one study, by Ribu et al. (2006) that examined the association between diabetic foot ulcer pain and the clinical variables. However, none of the socio-clinical variables (type of diabetes, HBA1c, body mass index, diabetes duration, number of late complications, number of comorbidities, treatment, ulcer size, wound location, duration of ulcer, severity of ulcer, type of foot ulcer complication, sensory examination and vascular examination) was associated with diabetic foot ulcer pain.

A comparison of the relationships between pain and clinical characteristics between patients in both clinics showed that there was a significant association between pain and the duration of diabetes mellitus, the number of comorbidities (more than three health problems), number of foot ulcer episode (3rd episode of foot ulcer), the site of the foot ulcer (forefoot), the severity of the ulcer (Wagner wound classification-Grade 4), the frequency of dressing (daily dressing), and the type of cleaning solution (sterile water) for patients in Clinic S. The results obtained were highly expected as they mainly represented the severity of the complications in people over sixty years with diabetic foot ulcers in Clinic S and could account for the higher pain among them. However, in Clinic P, pain was significantly associated with the severity of the ulcer (Wagner wound classification-Grade 3) and the type of dressing (antimicrobial) used. At the time this thesis was being written, this was the first study to compare pain and clinical characteristics in a secondary care clinic with those in a primary care clinic, within either a Malaysian or a Western context. Therefore, the results are unique, and there is no similar study to compare them with.

Further research is required to understand better the relationship between diabetic foot ulcer pain and clinical characteristics. Moreover, the association between diabetic foot ulcer pain and the frequency of dressing change, the type of cleaning agent, and the type of dressing has not been reported extensively in the literature; therefore, further research is needed to investigate this issue in more detail.

6.6.3 Association between pain and health-related quality of life

In recent years, there has been an increasing amount of evidence to suggest that living with diabetic foot ulcer pain has a huge impact on a patient's health-related quality of life (Ribu et al. 2007; Bradbury and Price 2011b; Bradbury and Price 2011c). Similar results were found in the current study, in which the generic health-related quality of life (SF-36) was significantly associated with diabetic foot ulcer pain. A negative correlation was found between pain and the seven SF-36 subscales: role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. This result suggests that patients who had a relatively worse health-related quality of life in role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health were more likely to report a higher intensity of pain.

In comparison with the only identified study that assessed perceived pain in diabetic foot ulcer patients using a similar scale, the SF-36, for measuring health-related quality of life, the pain was assessed using two items from the physical health domain of the DFS (Abetz et al. 2002) and by asking the patients whether they experienced any pain while walking/standing. Ribu et al. (2007) found that patients experiencing diabetic foot ulcer pain have consistently low scores in both the physical and the mental health domains.

When comparing the relationships between pain and the generic health-related quality of life for patients in both clinics, a negative correlation was found between pain and the six SF-36 subscales of role physical, bodily pain, vitality, social functioning, role emotional and mental health for those patients in Clinic S. This result suggests that patients in Clinic S who have a relatively worse health-related quality of life in role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health were more likely to report a

higher pain intensity. In contrast, a negative correlation was found between pain and the five SF-36 subscales of bodily pain, vitality, social functioning, role emotional, and mental health in Clinic P. This result suggests that people over sixty years with diabetic foot ulcers in Clinic P, who had a relatively worse health-related quality of life in bodily pain, vitality, social functioning, role emotional and mental health, were more likely to report a higher pain intensity.

The disease-specific health-related quality of life (DFS-SF) was significantly associated with diabetic foot ulcer pain in the current study. A negative correlation was found between all six subscales in the DFS-SF and diabetic foot ulcer pain. This result suggests that people over sixty years with diabetic foot ulcers, who have a relatively worse health-related quality of life in leisure, physical health, daily life, negative emotion, worried about ulcer, and bothered by ulcer care, were more likely to report greater pain intensity in both clinics.

This finding is consistent with that by Ribu et al. (2007), who studied 127 patients with diabetic foot ulcers using a disease specific measurement, that is, the DFS (Abetz et al. 2002). It was found that there were significant differences amongst the three pain groups in all the DFS subscales except in positive attitudes. Although the study samples were small, and the study was carried out using a different measurement tool, population, and setting, the findings are similar and suggest that diabetic foot ulcer pain can reduce health-related quality of life.

Similarly, findings from qualitative research have provided a description of the patients' pain experience and health-related quality of life. This can be seen in the study by Bradbury and Price (2011b) and Bradbury and Price (2011c [phase 2]). The study found that as a result of diabetic foot ulcer pain, patients were affected physically and psychologically especially with regard to mobility, sleep, and social life.

After making a comparison of the associations between pain and disease specific health-related quality of life for patients in both clinics, it was found that the results were comparable for both. This suggests that people over sixty years with diabetic foot ulcers and who had a relatively worse health-related quality of life in leisure, physical health, daily life, negative emotion, worried about ulcer,

and bothered by ulcer care were more likely to report greater pain in both clinics.

People with diabetes experience a reduced quality of life as compared to the healthy population, particularly if they have other associated co-morbid conditions such as heart disease (Darvishpoor and Abed 2013). Although the pain associated with having a diabetic foot ulcer can contribute to poor quality of life, having diabetes as well as other associated complications will also have effects which were not measured in this study.

In summary, the current study has shown how health-related quality of life was assessed using generic and disease-specific measurement tools. The results have shows that diabetic foot ulcer pain is very much related to health-related quality of life in Malaysian people over sixty years. This has been supported by studies conducted in Norway, despite the fact that their measurement tools or populations were different. Furthermore, at the time this thesis was being written, this was the first study to compare pain and health-related quality of life in a secondary care clinic with those in a primary care clinic, within either a Malaysian or a Western context. Therefore, the results are unique, and there is no similar study to compare them with.

6.6.4 Association between pain and the functional status

Diabetic foot ulcers are normally associated with pain and with restrictions in normal daily activities as well as being known to interfere in normal life. The majority of research into diabetic foot ulcer pain and health-related quality of life confirmed that the impact was especially significant on the physical aspects of a patient's daily life (Ribu and Wahl 2004; Bradbury and Price 2011b; Bradbury and Price 2011c [phase 2]; Obilor and Adejumo 2014). This finding supported the association between the self-care ADL (Katz ADL) and diabetic foot ulcer pain in the current study. A negative correlation was found between pain and the self-care ADL (Katz ADL). Similarly, the IADL (Lawton IADL) was also significantly associated with diabetic foot ulcer pain in the current study. A negative correlation was found between pain and the IADL (Lawton IADL). Both findings suggest that people over sixty years with diabetic foot ulcers, and who

have a comparatively worse functional status, are more likely to report a higher intensity of pain.

When comparing the association between pain and the functional status of patients in both clinics, the results were found to be comparable. The results suggested that people over sixty years with diabetic foot ulcers, and who had worse functional status, were more likely to report a higher intensity of pain, and this was true for both clinics. At the time this thesis was being written, this was the first study that compared pain and functional status in a secondary care clinic with those in a primary care clinic, within either a Malaysian or a Western context. Therefore, the results are unique, and there is no similar study to compare them with.

In summary, the findings on functional status and diabetic foot ulcer pain in the current study agreed with those of previous studies, even though no study was found that used the Katz ADL and the Lawton IADL to measure functional status as well as diabetic foot ulcer pain. Future studies on the effects of diabetic foot ulcer pain on functional status are therefore recommended.

6.7 The predictors of diabetic foot ulcer pain

The fifth objective of the current study was to investigate the predictors of pain in people over sixty years with diabetic foot ulcers in Malaysia.

In order to explore the factors that influence diabetic foot ulcer pain, simple and multiple linear regressions were used in the current study. In the simple linear regression, pain was regressed against 65 independent variables in turn, which were selected as being of potential importance in predicting diabetic foot ulcer pain. These included age categories (60-69, 70-79, 80 & above), gender (male, female), race, religion, marital status (single, married, widowed+ divorced+ separated), level of education (never, primary, secondary, tertiary), number of additional floors in the house, duration of diabetes mellitus, duration of foot ulcer, number of other co-morbid (0, 1, 2, more than 3), foot ulcer episode (1st episode, 2nd episode, 3rd episode, more than 3 episodes), site of foot ulcer (forefoot, midfoot, hindfoot), type of cleaning solution (saline, sterile water, Prontosan, Hydrocyn, Dermacyn), type of dressing (dry gauze, wet saline soaked, antimicrobials, gel dressing, foam), frequency of dressing (daily, every

alternate day, once a week, when needed), Wagner wound classification (Grade 1, Grade 2, Grade 3, Grade 4), SF-36 physical functioning, SF-36 role physical, SF-36 role emotional, SF-36 vitality, SF-36 mental health, SF-36 social functioning, SF-36 bodily pain, SF-36 general health, DFS-SF leisure, DFS-SF physical health, DFS-SF daily life, DFS-SF- negative emotion, DFS-SF worried about ulcer, DFS-SF bothered by ulcer care, Katz ADL, and Lawton IADL. In simple linear regression, 27 variables appeared to be significant predictors of pain ($p< 0.05$). These 27 variables were included in the multiple linear regression: gender, number of other co-morbidities: more than 3, duration of diabetes mellitus, 3rd episode of foot ulcer, forefoot, midfoot, sterile water, dermacyn, antimicrobials, gel dressing, daily dressing, Grade 1, Grade 3, Grade 4, SF-36 role emotional, SF-36 vitality, SF-36 mental health, SF-36 social functioning, SF-36 bodily pain, DFS-SF- leisure, DFS-SF- physical health, DFS-SF- daily life, DFS-SF- negative emotion, DFS-SF- worried about ulcer, DFS-SF- bothered by ulcer, Katz ADL, and Lawton IADL. The multiple linear regression analysis revealed that being female, suffering a Grade 4 foot ulcer, using sterile water, having antimicrobial dressings, experiencing bodily pain, and being bothered by ulcer care were the significant predictors of diabetic foot ulcer pain, and the analysis explained about 52% of the variance in the SF-MPQ. A Grade 4 ulcer was the strongest predictor of diabetic foot ulcer pain ($B=12.73$, indicating that people over sixty years with a Grade 4 foot ulcer experienced 13 times higher pain score). People over sixty years with diabetic foot ulcers who used antimicrobial dressings had a 7 times higher pain score. Meanwhile, for people over sixty years with diabetic foot ulcers who used sterile water as a cleansing agent, experiencing bodily pain and being bothered by ulcers were likely to be important factors affecting diabetic foot ulcer pain in the current study; however, their impact was lessened by the confounding effects of a Grade 4 foot ulcer and antimicrobial dressings. In particular, the effect for bodily pain ($B=-0.06$, $p=0.009$) was small and only just of statistical significance.

To the best of the researcher's knowledge, this is the first study that has examined the factors associated with diabetic foot ulcer pain using a multiple linear regression analysis. While it appears that there has been no study examining the predictors of diabetic foot ulcer pain, this comparison has been explored in other chronic wounds. For example, Hopman et al. (2013) examined

the relationship between demographics, clinical characteristics, pain, and health-related quality of life in 564 patients with active venous ulcers. There were several differences that have been identified compared to the current study. Firstly, the significant predictors were a younger age, living with others, and suffering from arthritis. Secondly, its adjusted R-square was only 4%.

In summary, it is difficult to compare the results of the current study with those of other studies that considered predictors of pain due to the differences in the type of wound or pain. Future studies would be needed to identify the predictors of diabetic foot ulcer pain in Malaysia.

6.8 The use of clinic among people over sixty years with diabetic foot ulcers in Malaysia

The sixth objective of the current study was to examine the health care clinic use by people over sixty years with diabetic foot ulcers in Malaysia.

6.8.1 Information and provision about wound pain control

It was found that people over sixty years with diabetic foot ulcers in the current study highlighted the need of being given more information about their wound pain control from the medical staff involved in their care – this was lacking in either a verbal or a written format. Moreover, a majority of them also reported that no one had provided them with any information about wound pain control, which is probably because there was a misconception that patients with diabetic foot ulcers do not experience pain as a result of peripheral sensory neuropathy complications associated with diabetes mellitus (Upton et al. 2013), which has been proven to be otherwise. A similar situation can be seen in venous ulcers and pain, in which it has been generally accepted that arterial ulcers are more painful than venous ulcers (King 2003; Benbow 2006). However, a number of studies have discovered that venous ulcer pain could also be severe and debilitating for patients (Ebbeskog and Ekman 2001; Hopman et al. 2013).

This scenario was similar for both clinics, as the results obtained were comparable in the sense that the people over sixty years with diabetic foot ulcers did not receive sufficient information about wound pain control in either a

verbal or a written format. Furthermore, they also reported that no one had provided them with any information about wound pain control.

6.8.2 Satisfaction with wound care

A patient's satisfaction with the nursing care remains an important factor in explaining patients' perceptions of the service quality. The findings of the current study have shown that a majority of the patients were satisfied with the wound care provided, and this finding is similar to that of others studies that assessed patients' satisfaction with nursing care (Akhtari-Zavare 2010; Sharma and Kamra 2013; Wai et al. 2013). The finding did not come as a surprise, as it reflects the culture and attitude of most Malaysians, who are generally not very critical when evaluating a service they have received. Moreover, in the Malaysian context, age and satisfaction could be due to cultural values instilled in individuals, as older people are often respected compared to younger people, and this could be the reason why the nurses paid more attention to them.

This scenario is similar for both clinics, as the results obtained were comparable in the sense that the people over sixty years with diabetic foot ulcers receiving care from both clinics were satisfied with the wound care provided.

6.8.3 Comments and suggestion by Malaysian people over sixty years with diabetic foot ulcers to improve the quality of health services at the clinic

The participants of the current study, which were Malaysian people over sixty years with diabetic foot ulcers, have put forward a number recommendations which can be considered in the quest to improve the quality of health care in the country. The issues highlighted include staffing, the long waiting hours, follow-ups, the attitude of healthcare professionals, the availability of up-to-date information, and the high cost of treatment. A comparison between both clinics showed there were some similarities and differences in the issues that emerged, and these are discussed below.

A shortage in the number of nurses is a major problem in healthcare settings in most parts of the world. Thus, it was not a surprise when many people over

sixty years with diabetic foot ulcers expressed their desire to have more nurses and doctors at both clinics, particularly in the wound care domain. The same high expectation also came from people over sixty years who were being treated at Clinic P, with a number of them wishing specifically that there were more male nurses in these clinics. Jarrar et al. (2015) stated that the shortage of nurses and the inadequate training of hospital nurses may jeopardize the quality of care as well as patients' safety. In order to address this issue, and as one of the efforts to strengthen the country's healthcare capacity, the Malaysian government has taken a strategy to increase the number of students undertaking nursing courses and thereby increase the supply of new graduates (Barnett et al. 2010).

The frustration of having to wait too long to be seen by a doctor, to collect medicine, and to receive treatment has been a long-standing issue not only in all outpatient clinics in Malaysia, but also in other countries. Several studies that were carried out in other Malaysian states, particularly a study that was conducted by Raja Lexshimi et al. (2009) at the National University of Malaysia Medical Centre in Kuala Lumpur, and another study by Al-Hadad et al. (2010), which was conducted in the state of Penang, have shown that a long waiting time will result in patients feeling dissatisfied with the hospital services. This may affect the quality of healthcare being provided. Findings from the two studies above are similar to the findings of the current study, as the majority of the patients in both clinics experienced long waiting times. This could probably be due to the large number of patients waiting to see a relatively small number of doctors. Other contributing factors could also be the ineffectiveness of the given appointment time and the appointment system (clustered appointment system) (Raja Lexshimi et al. 2009) for the two clinics. All patients in the clinic were given clustered appointments that were from 8:00 am to 11:00 am. This caused the patients to have to wait longer, as the registration at the counter only started at 8:00 am. In addition, the long waiting time may also be due to the type of treatment received, as some treatments may require more time than others. For example, a wound dressing procedure usually takes 30 minutes to 2 hours, but can vary depending on the patients' wound conditions. Based on the researcher's observations, a majority of the nurses in both clinics took within 30 minutes to 2 hours to complete a wound dressing procedure.

In terms of follow ups for patients, it was found that the duration for follow-ups in Clinic P did not meet the participants' expectations. The long duration could probably be due to the frequency of the dressing change, which is highly dependent on the type of dressing material used. For example, a hydrogel dressing may have to be changed every three days (Weller and Sussman 2006). Educating patients about the type of wound management is crucial. It can help them to gain knowledge of the type of dressing or cleansing that they need. Furthermore, educating the patients can enhance treatment adherence and optimise patient outcome (Price et al. 2007). However, it was observed that there was a lack of communication or discussion regarding the patient's wound dressing between the nurses or doctor and the patient. The possible explanation for this is the large number of patients, which put pressure on the nurses to expedite the wound treatment process so that all the patients could be attended to. Another reason could be that the nurses are responsible for ensuring that the clinic's operations are kept within office hours.

The attitude of health care professionals was reported in different ways in both clinics, with a majority of the people over sixty years feeling satisfied as they had received the necessary support and care from the nurses as well as the doctors. This may be due to the frequent visits to the clinic for wound dressing and the long involvement of patients; especially those with diabetic foot ulcers, which means that they begin to develop a good rapport with the health care professionals. According to Aljunid (1995), patients who frequently visit the clinic would have a change of perception or adaptation and would indirectly follow the requirements of the hospital services. On the other hand, one patient reported dissatisfaction with the attitude of both the nurses and the doctors.

As mentioned previously, the public health care system in Malaysia is funded from central taxation. However, there were instances when patients were also required to purchase medications that were not supplied by the government hospitals or clinics. Therefore, a patient in Clinic P commented that the cost of buying the wound cleansing solutions was quite high.

In terms of providing up-to-date information to the patients, one of the participants who were being treated in Clinic P pointed out that the clinic website was not being updated regularly. Generally, the website provided useful

information related to clinic activities, directories, and the type of services available. The website also provided useful information about communicable and non-communicable illness, such as information on self-care diabetes mellitus management. Therefore, it is crucial for the administrators of the clinic to ensure that the clinic website is updated with the latest information. Moreover, it is believed that social media such as the website can be used as a platform for information dissemination as well as being a medium for interaction among patients and healthcare professionals (Podichetty et al. 2006).

6.9 Summary

Pain was experienced by all the 300 people over sixty years with diabetic foot ulcers who participated in the current study, and the level of pain can be categorized between the ranges of 'mild' to 'severe'.

The findings on the duration of diabetes mellitus, number of comorbidities (more than three health problems), number of foot ulcer episodes (3rd episode of foot ulcer), site of the foot ulcer (forefoot), severity of ulcer (Wagner wound classification-Grade 4), frequency of dressing (daily dressing), type of cleaning solution used (sterile water) and the SF-36 (physical role) had a significant association with the SF-MPQ in the Clinic S. Malaysian people over sixty years with diabetic foot ulcers from the Clinic P who were female, had a Grade 3 in terms of the severity of ulcer (Wagner wound classification-Grade 3) and used antimicrobial dressings were likely to report a higher pain experience compared to a male patient, with a severity of ulcer of Grades 1, 2 or 4 (Wagner wound classification-Grade 1, 2, or 4), and using the gel dressing with a dry gauze type of dressing (gel dressing and dry gauze). Finally, participants in Clinic S reported much more pain compared to participants in Clinic P.

In the stepwise multiple linear regression, being female, having a Grade 4 foot ulcer, using sterile water, using an antimicrobial dressing, having bodily pain, and being bothered by ulcer care were the significant predictors of diabetic foot ulcer pain.

However, the participants also commented and suggested that several factors, such as the need for more nurses and doctors, the long waiting hours, the number of follow-ups, the attitude of healthcare professionals, the cost of

treatment, and having up-to-date information on the website, should be taken into consideration in order to improve the quality of health services at the clinics.

CHAPTER 7

CONCLUSIONS

7.1 Introduction

This chapter discusses the overview of the key findings in the study. Comments on the contributions of the study will be presented first followed by the strengths and limitations of the study, which are presented in the third section. Finally, the recommendations and implications of the findings as well as the conclusions of the study are presented towards the end of the chapter.

7.2 Contributions of the study

The current study makes an important contribution to the understanding of pain in people over sixty years with diabetic foot ulcers in Malaysia. A comparative cross-sectional study design was successfully used to quantitatively measure the pain in people over sixty with diabetic foot ulcers in Malaysia and explore the factors that were associated with pain. In particular, it provides insights into the association between pain and selected socio-demographic and clinical characteristics, health-related quality of life, and functional status in this older population. It was found that pain was experienced by all the sample of 300 people over sixty years with diabetic foot ulcers in Malaysia, and this was consistent with findings in other countries. It is important to note that this was the first study in Malaysia to estimate diabetic foot ulcer pain.

This was the first study to use five validated instruments to measure patient-reported outcomes for pain, health-related quality of life, and functional status in older individuals with diabetic foot ulcers. Following a comprehensive literature review, five validated tools were used to measure pain, namely, the SF-MPQ (Melzack 1987), the general health-related quality of life scale (SF-36) (Ware and Sherbourne 1992), the disease-specific health-related quality of life scale (DFS-SF) (Bann et al. 2003), the functional status (Katz ADL (Katz and Akpom 1976) and the Lawton IADL (Lawton and Brody 1969). These validated tools made it possible to investigate which factors were associated with and

potentially predictive of pain in this older population. The DFS-SF (Bann et al. 2003), the Katz ADL (Katz and Akpom 1976), and the Lawton IADL (Lawton and Brody 1969) were subjected to a forward-backward translation process into the Malay language, as these three tools were not available in that language. The rigorous forward-backward translation process was suggested by the Mapi Research Trust (2005). The reliability of these instruments was also tested in the current study, yielding satisfactory internal consistency (with a Cronbach's α coefficient of over 0.70).

Further contributions to new knowledge involved the data analysis of the study. This was the first study in Malaysia to investigate predictors of pain in older individuals with diabetic foot ulcers. With the increasing prevalence of diabetic foot ulcers among Malaysian people over sixty years, the findings from the current study offer some solutions in improving their health management and assist nursing staff in understanding the important factors that might cause pain in patients with diabetic foot ulcers.

7.3 Strength and limitations of the study

7.3.1 Study design

A cross-sectional comparative survey design was selected for the current study which aimed to investigate the relationships between diabetic foot ulcer pain and health-related quality of life and functional status among people over sixty years in Malaysia. This research design was found to be effective for collecting detailed information from large numbers of people at a specific time (Kelly et al. 2003). It also made possible the description of relationships among a variety of variables at a fixed point. However, the causal relationship between the related factors and diabetic foot ulcer pain is yet to be identified. Nevertheless, the current study contributes to the understanding of pain in people over sixty years with diabetic foot ulcers in Malaysia, which can be viewed as a starting point for further research.

7.3.2 Study setting

The study was conducted in hospitals as well as in community clinics in Kuala Lumpur and Selangor, which are the locations for referral centres from the whole of Malaysia, thus providing the researcher with a reasonable representation of the older population with diabetic foot ulcers in the country. The findings were obtained from 300 participants, which is a large sample. In previous research, small sample size was a common limitation and this had impeded the full exploration of variables that may influence diabetic foot ulcer pain. The large sample from both secondary care and primary care settings is likely to be reasonably representative of the populations receiving treatment for diabetic foot ulcers. The researcher opines that the findings of the current study can be generalised to the majority of older diabetic foot ulcer patients in Malaysia due to the large sample size. Furthermore, the large sample size in the current study increased the likelihood of detecting a statistical relationship and of multivariate analyses, such as regression, and producing reliable results.

7.3.3 Higher response rate

The key strength of the current study was the high participation rate of patients; Clinic S (99%) and Clinic P (100%). Two patients declined to take part as they were not interested in participating in the study, and their family did not support their involvement in the study. On the other hand, some of the people over sixty years expressed their pleasure in being able to share their viewpoint and found benefits in communicating with the researcher about their experiences with diabetic foot ulcer pain.

7.3.4 Sample and sampling strategy

A consecutive sampling technique was used in the study. This type of sampling is considered the strongest form of non-probability sampling (Polit and Beck 2012). This sampling made it possible for the researcher to include all the patients who met the inclusion criteria of the study. Thus, the sample was more likely to be a better representation of diabetic foot ulcer patients who visited the clinics for follow-up during the current study period.

However, the findings may not be generalized to the populations of people over sixty years with diabetic foot ulcers who live in rural areas or other geographical regions in Malaysia. This is because Kuala Lumpur and Selangor are two commercially and industrially driven cities, as well as being known as the two most developed areas in Malaysia. Therefore, the study was very much focused on those living in urban areas. Their demographic characteristics, clinical characteristics, pain experiences, health-related quality of life, and functional status may differ from those who live in rural areas. However, it could be argued that as the participants were recruited from a hospital-based Clinic S and a community-based Clinic P, and Clinic S is a referral centre for patients from all over the country, therefore, the patients come from both urban and rural areas in Malaysia. These patients had varied socio-economic, cultural, and educational backgrounds. Therefore, they provide a representative cross-section of the population, thus allowing for generalization of the study results.

7.3.5 Instruments

The study was carried out using five widely used validated questionnaires to collect subjective measurements from participants on their pain, health-related quality of life, and functional status (the SF-MPQ, SF-36, DFS-SF, Katz ADL, and Lawton IADL respectively). The Malay language versions of these questionnaires were used in the study. Reliability was assessed in terms of having internal consistency coefficients (Cronbach's alpha) in the range of 0.7 to 0.9. Unfortunately, the researcher was unable to conduct test–retest reliability because of the appointment duration for each diabetic foot ulcer patient. This suggests that the test-retest reliability testing should be carried out and adapted for use in Malaysia.

7.3.6 Method of data collection

For the current study, data were collected through an interviewer-administered questionnaire. This mode of data collection is especially suitable for older people, as it is the least burdensome method; it requires no expectations of reading skills by the participants, but only basic verbal and listening skills (Bowling 2005). Another advantage of this method is the opportunity for the researcher to clarify any uncertainties and ambiguities to minimise errors in the

responses. Moreover, interviewer-administered questionnaires are known to yield higher response rates; this was demonstrated in the current study, where there were no incidents of missing data. In addition, it is preferred by participants (Bowling 2005). The participants were given a small gift, such as a towel, as a token of appreciation for their participation, which may also have been a factor for an increase in the response rate. The practice of giving out tokens of appreciation to participants of any study in Malaysia is a common cultural trait as a way of expressing one's gratitude. However, this method has some disadvantages in the sense that the participants have the tendency to give more socially desirable and positive responses (Bowling 2005). In addition, the current study was conducted solely by the researcher, and she found that this method was time-consuming.

From the researcher's observation, administering questionnaires to patients in the hospital clinics could have had a social desirability effect as they might have felt obliged to report high levels of satisfaction with their care. Based on the researcher's experiences with some of the patients, it was found that the reason for doing so was due to the fact that they mistakenly thought the researcher was a member of hospital staff or they were anxious about the hospital staff learning about negative perceptions of the care provided. Should the data have been collected outside the hospitals, some patients would have probably expressed greater dissatisfaction with care.

During the study, it was found that the medical notes for many of the participants were not organized or, in some cases, were incomplete. Therefore, the researcher had to address four of the most important questions to the patients themselves, and these included the duration of diabetic mellitus, the duration of foot ulcer episodes, the number of co-morbidities, and the perceived cause of the diabetic foot ulcer, with some exceptions where the information was available from the medical notes. However, it is important to note that the data were obtained from the older people themselves, and self-report measures may be subject to distortion and bias. For example, some of the older people may not have been able to remember their chronic diseases or may not have described their chronic diseases correctly. Thus, the number of chronic disease might be inaccurate, and so the effect of the number of chronic diseases upon

pain may not be properly represented. This could be a major setback which could undermine the validity of the results.

Another limitation of the current study is that there was no information regarding the patients' diabetic foot ulcer aetiology status in the patients' medical notes. Therefore, the current study did not examine the category of each diabetic foot ulcer based on its aetiology: neuropathic, ischaemic, or neuroischaemic. This suggests that further research should be carried out in Malaysia to determine the characteristics of wound-related pain associated with diabetic foot ulcers of various aetiologies.

Apart from that, the current study did not focus on the variety of self-management strategies regarding diabetic foot ulcers. In the questionnaire of self-management strategies, the participants were required to select only one strategy. However, the researcher believed that it is quite common for patients to have more than one. Therefore, in future studies, a more in-depth investigation of self-management strategies could be conducted.

7.3.7 Appropriateness of statistical methods

The data obtained were analysed thoroughly, in accordance with the relevant study objectives. The distribution of the SF-MPQ in the study was skewed, and therefore, non-parametric univariate analyses were used to determine the relationship between diabetic foot ulcer pain and the socio-demographic and clinical characteristics, the health-related quality of life, and functional status. Non-parametric tests are accurate tests; however, non-parametric tests are considered less sensitive and precise than parametric tests (Portney and Watkins 2009). The findings are, therefore, less powerful and precise when it comes to generalising them to other types of patients. Predictors of diabetic foot ulcer pain were investigated using simple and multiple linear regressions. The underlying assumptions for the different approaches were carefully assessed in order to increase confidence in the reliability of the observed findings.

Generally, according to Field (2009), when a dependent variable does not follow the normality assumption, transformation can be carried out to so that the data will follow a normal distribution. However, the transformation of data was not performed in the current study. This is due to the fact, as described in

Section 4.3.2, in order to ensure that those 27 important predictors accurately contribute to diabetic foot ulcer pain, the assumptions of multiple regression that were assessed in the study include: sample size, multicollinearity, outliers, normality, linearity and homoscedasticity. The assumptions appeared to be satisfying, therefore, it can be assumed that the regression models were reliable and adequately summarised the contributions of the included predictors of diabetic foot ulcer pain.

Moreover, R^2 in the data analysis is 0.52%, which means that 52% of the variance SF-MPQ is explained by the combination of independent variables. The R^2 is an important measure which indicates how much of the variance in a dependent variable is accounted for by the different predictors in the model (Pallant 2013). According to Pallant (2013) a value around 0.45 for the R^2 is a respectable result. For these two reasons, the transformation of data was not performed.

7.4 Implications of the study

The findings of the study have significant implications on nursing practice, nursing services, and nursing research. These implications will be addressed according to nursing practice and policy, as well as nursing education.

7.4.1 Implication on the nursing practice and policy

The current study measured diabetic foot ulcer pain in people over sixty years with diabetic foot ulcers in Malaysia and examined its relationship with health-related quality of life and functional status. Findings from the study suggest the following implications for nursing practice and policy in Malaysia:

- The findings of the study indicate that all the participants had experienced diabetic foot ulcer pain. Several factors were identified as influencing the pain. These factors include being female, being married, the shorter duration of diabetes mellitus, having more than three health problems, having a 3rd episode of foot ulcers, the ulcer being at the forefoot, and having a grade 3 or grade 4 foot ulcer. Therefore, it is crucial that a detailed assessment is carried out to determine these factors. This will enable nurses to plan and

deliver specific intervention for people over sixty years with diabetic foot ulcers who experience pain, as planning and delivering specific intervention is a significant issue in nursing care.

- The current study also indicates that there is a need for an increased awareness amongst healthcare professionals, especially nurses, on matters such as the early detection, prevention, and adequate management of pain in people over sixty years with diabetic foot ulcers. All patients with diabetic foot ulcers should be screened regularly for pain using a validated instrument, such as the VAS or the SF-MPQ. After the screening, patients with pain should be treated in accordance with a strict pain protocol.
- Nurses need to be aware that pain is significantly associated with reduced health-related quality of life and functional status. Therefore, in providing the care for people over sixty years with diabetic foot ulcers, it is necessary for the nurses to pay attention to their health status; to daily activities, such as bathing and cooking, mobility, and travelling arrangements; and family relationships.
- The current study indicates that change of dressing, type of cleansing agents and type of dressing agents can be the cause of wound pain. Thus, it is important for nurses to be aware of these factors when performing procedures such as dressing removal, debridement, and selecting wound care products. In most cases, the nurses often assumed that these procedures could be performed without causing pain to the patients due to the presence of neuropathy (Bradbury and Price 2011c). Additionally, nurses can provide analgesia before dressing change or other wound procedures that can cause pain.
- All nurses have the responsibility to prevent patients from having unrelieved pain. This requires a collaboration with committed, dedicated professionals including wound care specialists, pain specialists, podiatrists, endocrinologists/physicians, and nurses to promote better assessment and management of diabetic foot ulcer pain and its relationships with health-related quality of life and functional status.
- From the literature review, it was found that diabetic foot ulcers pose a substantial problem in the Malaysian diabetes mellitus population. The Malaysian government needs to report on the prevalence of diabetic foot

ulcers regularly to their people, perhaps in the form of an annual report, in order to raise their awareness of this chronic illness.

- To date, there are still no guidelines on diabetic foot ulcer pain assessment and management in Malaysia. For example, there is no mention of pain and pain relief in the current guidelines of the management of diabetic foot ulcers (Ministry of Health Malaysia 2004). Therefore, the government and health authorities should amend the clinical guidelines for the management of diabetic foot ulcers by adding non-pharmacological and pharmacological treatments for diabetic foot ulcer pain.
- One of the challenges faced by the researcher while reviewing the medical notes was the fact that they were disorganized, incomplete and in some cases illegible. This is an issue that should be addressed by the government. An improved method in both electronic as well as manual records should be practised for easy accessibility to the records by authorized individuals, such as the healthcare professionals.

7.4.2 Implications for education

7.4.2.1 Nursing education

The current study has implications which are relevant to nursing education in nursing schools and in the in-service education of health care institutions. Nurses require continuous education programs and training to build and refresh their existing knowledge and practice on the importance of providing effective evidence-based wound management. An education system with a greater emphasis on diabetic neuropathic pain management, foot ulcer assessment, and the strategies needed to overcome pain is therefore required. Furthermore, it is also important for the nurses to have knowledge which is up-to-date especially on dressing techniques and the type of wound care products in order to minimise pain, odour, and exudate.

As it was previously assumed that diabetic foot ulcer patients do not experience pain due to the presence of neuropathy or can only feel pain in the presence of complications, it is essential that information about the presence, characteristics, and impacts of diabetic foot ulcer pain be discussed in

continuing education programs and seminars. With an increased knowledge and a better understanding of diabetic neuropathic pain, nurses will be well aware of its existence while ensuring that thorough assessments and treatment regimens are considered.

Another important impact that the current study has on nursing education is that nursing educators may use the results and incorporate them in their teaching strategic plans. Nursing educators may introduce lessons on diabetic neuropathic pain and its relationships with health-related quality of life and functional status, and pain assessment techniques and management in the nursing curriculum. This could be a main component in undergraduate nursing programmes, to prepare future nurses to provide culturally competent nursing care for diabetic foot ulcer patients suffering from pain. Furthermore, nurses who are able to understand a patients' diabetic foot ulcer pain will be able to provide effective pain and wound assessment and identify any signs of improvement or deterioration, which will ensure early interventions are instigated.

7.4.2.2 Patient education

The findings of the study indicate that people over sixty years with diabetic foot ulcers do not receive adequate information regarding wound pain control and the recommended frequency of wound dressing change. Education is a key strategy in successfully managing chronic wound pain (Price et al. 2007). Specific intervention programs, such as adequate information on diabetic foot ulcer pain, analgesia, and pain management, should be planned and implemented. In the intervention programs, people over sixty years with diabetic foot ulcers should also be informed about wound management, such as how wound care products can remain in place for several days, thus reducing the need for frequent and painful dressing changes. This information should be delivered in accordance with people over sixty years's level of understanding to ensure that the information has been well disseminated. A sound knowledge of their disease will encourage and empower them to participate actively in their management; thus, effective self- management of diabetic foot ulcer pain will be achieved.

7.5 Recommendation for future research

The current study employed a number of validated questionnaires used to investigate pain, health-related quality of life, and functional status in the study population of people over sixty years with diabetic foot ulcers in Malaysia. It provided evidence on the degree of pain experienced and its association with socio-demographic characteristics (being female and married), clinical characteristics (shorter duration of diabetes mellitus, having more than three health problems, having a 3rd episode of foot ulcers, having a foot ulcer at the forefoot, suffering with Grade 3 or 4 foot ulcer, undergoing daily dressing changes and using sterile water and antimicrobial dressings), health-related quality of life, and functional status. It has led to a number of recommendations for future study in this population of people over sixty years with diabetic foot ulcers living in the community:

1. It is recommended that a mixed methods approach is used to explore the experiences of people over sixty years with diabetic foot ulcers to gain a more all round understanding of the following:
    - perceptions of pain, health-related quality of life, and functional status of this group of people, to verify the findings of the current study
    - experience of living with diabetic foot ulcer pain from the perspectives of people over sixty years, such as in assessing the presence of diabetic foot ulcer pain prior to, during, and after dressing change; coping strategies, pharmacological and non-pharmacological treatment; and social supports could also be obtained from in-depth interviews.
    - The experience of self-management of diabetic foot ulcers and whether this has an impact on people over sixty years's pain.
2. Additional research conducted in rural area or other cities of Malaysia using the same measurement is recommended to compare the pain experienced, health-related quality of life, and functional status of people over sixty years with diabetic foot ulcers in these areas. This will help to influence clinical practice, as well as improving the care delivered to patients with diabetic foot ulcers.
3. As mentioned previously in the research limitation section, the current study did not examine the category of the diabetic foot ulcer based on its

aetiology, that is, neuropathic, ischaemic, or neuroischaemic, as there was no information regarding the patients' diabetic foot ulcer aetiology status in their medical records. Therefore, further quantitative research that would determine the characteristics of pain associated with diabetic foot ulcers of various aetiologies is needed.

4. Further research should be carried out to investigate the relationship between diabetic foot ulcer pain and ulcers at multiple sites.
5. There is a need for further research to explore the various types of self-management strategies adopted by patients with diabetic foot ulcers in order to reduce their foot pressure.
6. Longitudinal studies are recommended to identify any causal relationships between the studied independent and dependent factors, such as health-related quality of life and pain.
7. The multiple linear regression results have shown that sterile water and antimicrobial dressings were predictors of pain. Intervention studies are required to compare between sterile water, antimicrobial dressings, and other types of modern dressing.
8. In addition, the Malay DFS-SF, the Malay Katz ADL and the Malay IADL need to be tested further with a wider range of people over sixty years. Test-retest reliability is required to assess the stability of the Malay DFS-SF, the Malay Katz ADL and the Malay IADL by correlating the scores obtained on two administrations.

7.6 Summary

This cross-sectional comparative study investigated diabetic foot ulcer pain and its association with health-related quality of life and functional status in people over sixty years with diabetic foot ulcers in Malaysia. The current study supports the published literature that diabetic foot ulcer pain is an underestimated phenomenon experienced by patients and can have a severe impact on health-related quality of life and functional status.

The implications of this research for practice, policy making, and education have been identified, and recommendations for further research have been made. In particular, the current study provides a means for healthcare providers to identify areas that can be improved in implementing wound prevention

programs for patients with diabetes mellitus as well as to improve treatment of patients with diabetic foot ulcers by including holistic assessment and a better management of diabetic foot ulcer pain.

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Zanariah, H. et al. 2008. Prevalence of diabetes mellitus in Malaysia in 2006 – results of the Third National Health and Morbidity Survey (NHMS III). *Diabetes Res Clin Pract* 79, pp. 2.

Appendix 1: List of keywords used in literature search and detail of search strategy

	Search terms	CINHAL	MEDLINE-OVID	BNI
1	Foot ulcer	5343	5636	301
2	Diabetic foot ulcer	255	318	414
3	Combined 1 OR 2	5360	5662	414
4	Pain	142349	279682	7609
5	Health related quality of life	6954	16591	527
6	Quality of life	66086	138688	6090
7	Wellness	6303	2827	184
8	Well-being	20234	26112	1437
9	Combined 5 OR 6 OR 7 OR 8	88270	159660	7280
10	Functional status	15341	10986	235
11	Activity daily living	3	15	252
12	Combined 10 OR 11	1612	11013	471
13	Combined 3 AND 4 AND 9 AND 12	190	37	13
14	Gel dressing	3580	334	124
15	Antimicrobial dressing	8090	760	343
16	Gauze dressing	514	114	544
17	Saline soaked	7680	345	678
18	Foam dressing	6718	436	789
19	Combined 3 AND 4 AND 15 AND 16 AND 17 AND 18	415	80	14
Total	**13 + 19**	**605**	**117**	**27**

Appendix 2: Licences for short-form McGill pain questionnaire, medical outcomes study 36-item short survey, diabetic foot ulcer scale short-form, Katz activity daily living and Lawton instrumental activity daily living

A 2.1: Permission to use short-form McGill pain questionnaire

Mapi™
Research Trust

Aniawanis Makhtar
16 Canton Court
CF11 9BG Cardiff
United Kingdom

Nom du contact :
Nos références : 35656 - 2093 - PB
Vos références :
N° client : 151760
Commande du : 16/10/2013

Lyon, le 26 May 2014

FACTURE N° 14-00433

SF-MPQ: Providing of the Questionnaire

SF-MPQ: Fourniture du Questionnaire

Distribution de questionnaires par Mapi Research Trust *Distribution of questionnaires by Mapi Research Trust*	**150.00 EUR**
Total HT :	**150.00 EUR**
TVA (20,00%) :	**30.00 EUR**
Total TTC :	**180.00 EUR**

Votre numéro de T.V.A. :

En votre aimable règlement dans un délai de 30 jours à la date de la facture :

- By bank transfer :
CIC RHONE CENTRE ENTREPRISES
8 rue de la République
69001 LYON - France

Numéro de compte : 00060598601 / Clé RIB : 51
Code Banque : 10096 / Code Guichet : 18505
IBAN: FR76 1009 6185 0500 0605 9860 151
SWIFT/BIC: CMCIFRPP

- By check :
MAPI RESEARCH TRUST
27 rue de la Villette
69003 LYON - France

- By credit card :
Online payment upon request

Passé ce délai, les sommes non payées supporteront un intérêt égal à trois fois le taux d'intérêt légal annuel sur une base mensuelle (article L441-6 du Code du Commerce). Tout retard de paiement de cette facture entraîne l'exigibilité d'une indemnité forfaitaire pour frais de recouvrement de quarante (40) euros (Article D.441 5 du code de commerce).
After the payment term indicated, the unpaid amount will be charged of a banking interest equal to three times the French legal annual interest rate on a monthly basi (Article L441-6 of the French Commercial Code). In the event of late payment of this invoice, MAPI is entitled to obtain from you a fixed sum of € 40 as compensation for recovery costs (Article D.441-5 of the French Commercial Code).

Bureaux Lyonnais : 27, rue de la Villette - 69003 LYON - France
Téléphone : +33 (0)4 72 13 65 75 - Fax : +33 (0)4 72 13 66 68

Association loi de 1901, enregistrée à la Préfecture de Carpentras sous le N° 0843004402 - TVA : FR 44 453 979 346

A 2.2: Permission to use medical outcomes study 36-item short survey

OPTUM

NON-COMMERCIAL LICENSE AGREEMENT
Office of Grants and Scholarly Research (OGSR)

License Number: QM023561

Licensee Name: Aniawanis MAKHTAR c/o Cardiff University

Licensee Address: 16 Canton Court, Canton, CARDIFF CF11 9BG, UK

Approved Purpose: Non-commercial academic research and/or thesis – Unfunded Student License Program

Study Name: The impact of diabetic foot ulcer pain on health-related quality of life and functional status in older adults

Study Type: Student Thesis/Dissertation

Data Collection Method: Paper

Therapeutic Area: Wellness & Lifestyle

Royalty Fee: None, because this License is granted in support of the non-commercial Approved Purpose

Other Definitions: As indicated on Appendix B "License Agreement – Details", including without limitation: Licensed Surveys, Modes of Administration, Fees, Administrations, Services, Approved Languages and (if applicable) Study Term

Licensee accepts and agrees to the terms of this Non-Commercial License Agreement (the "Agreement") from the Office of Grants and Scholarly Research (OGSR) of OptumInsight Life Sciences, Inc. (f/k/a QualityMetric Incorporated) ("OptumInsight") as of the date of last signature below (the "Effective Date").

Subject to the terms of this Agreement, including the OptumInsight Non-Commercial License Terms and Conditions attached as Appendix A: OptumInsight grants to Licensee, and Licensee accepts, a non-exclusive, non-transferable, non-assignable, non-sublicensable worldwide license to use, solely for the Approved Purpose and during the License Term, the Licensed Surveys in the authorized Data Collection Methods, Modes of Administration, and Approved Languages indicated on Appendix B and to administer the Licensed Surveys only up to the approved number of Administrations (and to make up to such number of exact reproductions of the Licensed Surveys necessary to support such Administrations) in any combination of the specific Licensed Surveys and Approved Languages, Data Collection Methods, and Modes of Administration and to use any related software provided by OptumInsight.

Capitalized terms used in this Agreement shall have the meanings assigned to them above, or in Appendices A and B attached hereto. Appendices A and B attached hereto are incorporated into and made a part of this Agreement for all purposes.

EXECUTED, as of the Effective Date, by the duly authorized representatives as set forth below.

OptumInsight Life Sciences, Inc. [OptumInsight]	**Aniawanis MAKHTAR c/o Cardiff University** [Licensee]
Signature: Michelle White	Signature: Ani
Name: Michelle White	Name: Aniawanis MAKHTAR
Title: Director of Consulting Science	Title: MRS
Date: 17 MAR 2014	Date: 13.3.2014

Filename: Cardiff University Aniawanis MAKHTAR
Lic. No.: QM023561 – CT158165 / OP034787
Template: OGSR Unfunded Student LA - 2014-01-13

an OptumInsight company

Page 1 of 5

A 2.3: Permission to use diabetic foot ulcer scale short-from

Mapi™
Research Trust

Aniawanis Makhtar
16 Canton Court
CF11 9BG Cardiff
United Kingdom

Nom du contact :
Nos références : 35654 - 2005 - PB
Vos références :
N° client : 151760
Commande du : 16/10/2013

Lyon, le 26 May 2014

FACTURE N° 14-00432

DFS-SF: Providing of the Questionnaire

DFS-SF: Fourniture du Questionnaire

Distribution de questionnaires par Mapi Research Trust *Distribution of questionnaires by Mapi Research Trust*	**150.00 EUR**
Total HT :	**150.00 EUR**
TVA (20,00%) :	**30.00 EUR**
Total TTC :	**180.00 EUR**

Votre numéro de T.V.A. :
En votre aimable règlement dans un délai de 30 jours à la date de la facture :

- By bank transfer :
CIC RHONE CENTRE ENTREPRISES
8 rue de la République
69001 LYON - France

Numéro de compte : 00060598601 / Clé RIB : 51
Code Banque : 10096 / Code Guichet : 18505
IBAN: FR76 1009 6185 0500 0605 9860 151
SWIFT/BIC: CMCIFRPP

- By check :
MAPI RESEARCH TRUST
27 rue de la Villette
69003 LYON - France

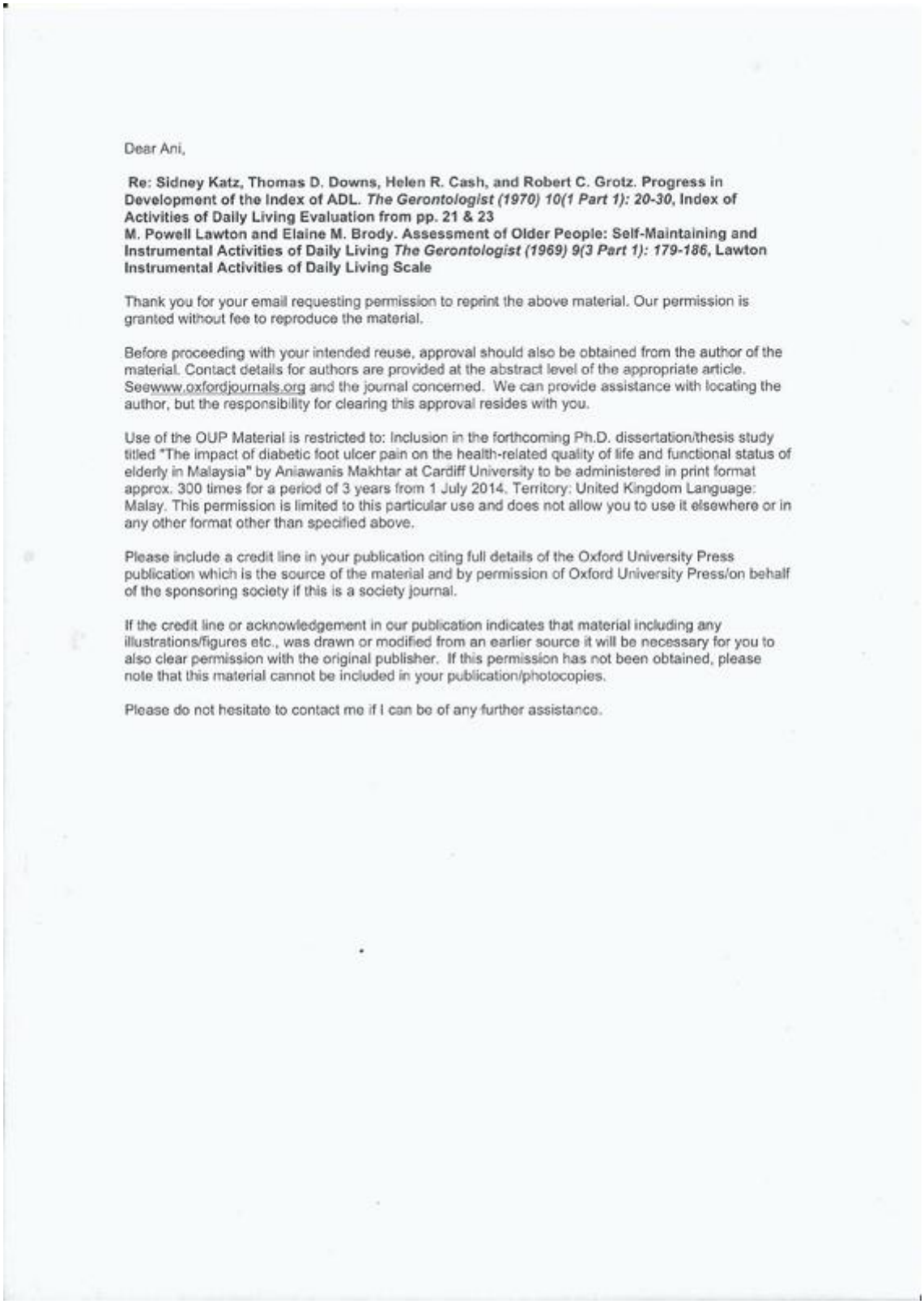
- By credit card :
Online payment upon request

Passé ce délai, les sommes non payées supporteront un intérêt égal à trois fois le taux d'intérêt légal annuel sur une base mensuelle (article L441-6 du Code du Commerce). Tout retard de paiement de cette facture entraîne l'exigibilité d'une indemnité forfaitaire pour frais de recouvrement de quarante (40) euros (Article D.441 5 du code de commerce).
After the payment term indicated, the unpaid amount will be charged of a banking interest equal to three times the French legal annual interest rate on a monthly basi (Article L441-6 of the French Commercial Code). In the event of late payment of this invoice, MAPI is entitled to obtain from you a fixed sum of € 40 as compensation for recovery costs (Article D.441-5 of the French Commercial Code).

Bureaux Lyonnais : 27, rue de la Villette - 69003 LYON - France
Téléphone : +33 (0)4 72 13 65 75 - Fax : +33 (0)4 72 13 66 68

Association loi de 1901, enregistrée à la Préfecture de Carpentras sous le N° 0843004402 - TVA : FR 44 453 979 346

A 2.4: Permission to use Katz activity daily living and Lawton instrumental activity daily living



Dear Ani,

Re: Sidney Katz, Thomas D. Downs, Helen R. Cash, and Robert C. Grotz. Progress in Development of the Index of ADL. *The Gerontologist (1970) 10(1 Part 1): 20-30*, Index of Activities of Daily Living Evaluation from pp. 21 & 23
M. Powell Lawton and Elaine M. Brody. Assessment of Older People: Self-Maintaining and Instrumental Activities of Daily Living *The Gerontologist (1969) 9(3 Part 1): 179-186*, Lawton Instrumental Activities of Daily Living Scale

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Please do not hesitate to contact me if I can be of any further assistance.

Appendix 3: Ethical approval

A 3.1: Ethical approval from Scool of Healthcare Sciences, Cardiff University

School of Health Care Sciences
Head of School and Dean Professor Sheila Hunt

Ysgol Gwyddorau Gofal Iechyd
Pennaeth yr Ysgol a Deon Yr Athrawes Sheila Hunt

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

06 May 2014

Cardiff University
Ty Dewi Sant
Heath Park
Cardiff CF14 4XN

Tel Ffôn +44(0)29 20687552
E-mail E-bost harmerl@cf.ac.uk
Prifysgol Caerdydd
Ty Dewi Sant
Mynydd Bychan
Caerdydd CF14 4XN

Aniawanis Makhter
School of Healthcare Sciences
Cardiff University
7th Floor
Eastgate House
35-43 Newport Road
CARDIFF
CF24 0AB

Reference ANI 01/05/14

Dear Ani

The impact of diabetic foot ulcer pain on the health-related quality of life and functional status of elderly in Malaysia

I am writing to inform you that the Chair of the Research Ethics Committee has, following consultation, approved your revised research proposal. The Committee will ratify this decision at its meeting on 29 May 2014

Please note that if there are any major amendments to the project you will be required to submit a revised proposal form. You are advised to contact me if this situation arises. In addition, in line with the University requirements, the project will be monitored on an annual basis by the Committee and an annual monitoring form will be despatched to you in approximately 11 months time. If the project is completed before this time you should contact me to obtain a form for completion.

Please do not hesitate to contact me if you have any questions.

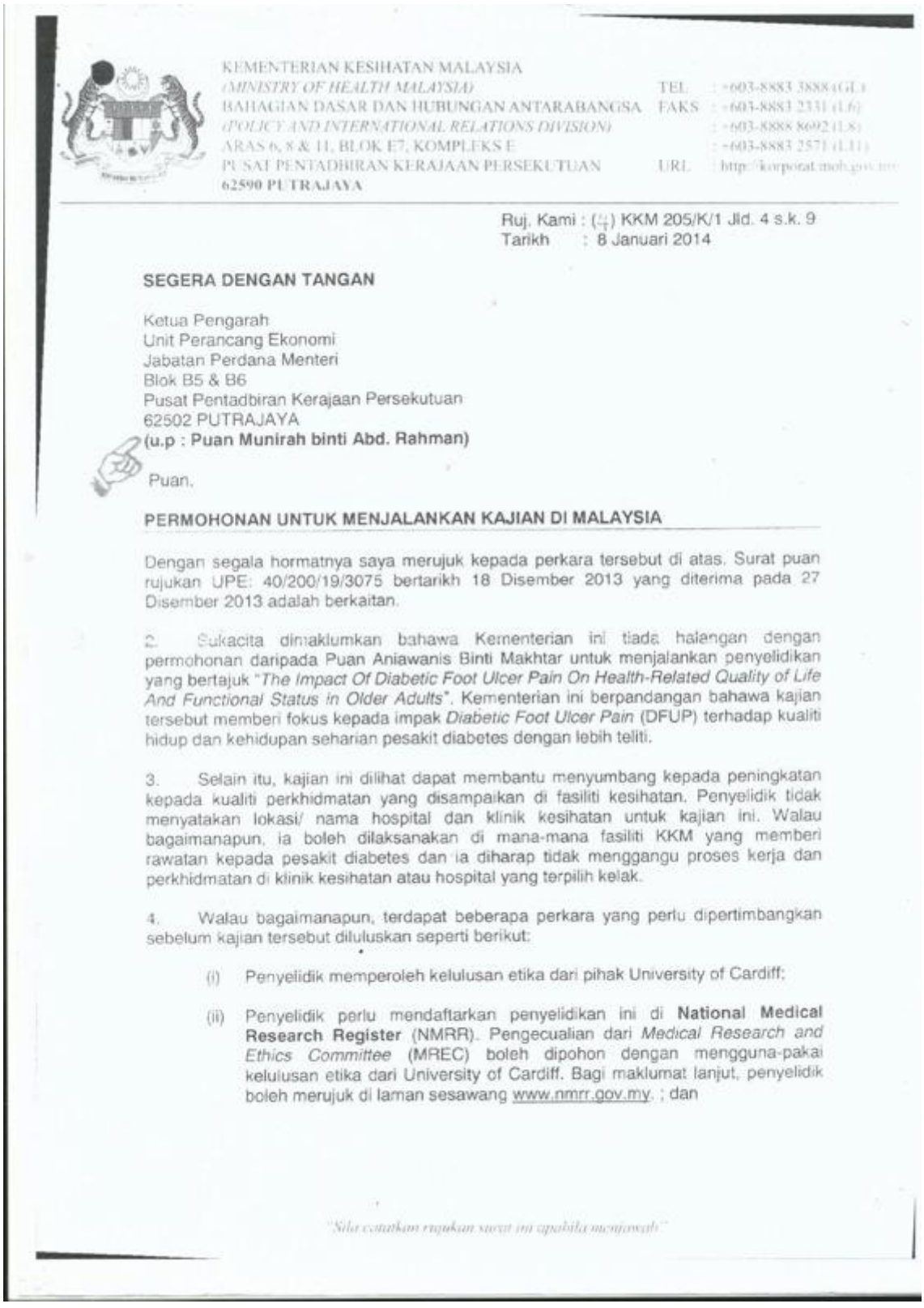
Yours sincerely

Liz

Mrs Liz Harmer Griebel
Research Administration Manager

Cc Professor Dinah Gould and Dr Sally Anstey - supervisors

A 3.2: Ethical approval from Ministry of Health Malaysia



KEMENTERIAN KESIHATAN MALAYSIA
(MINISTRY OF HEALTH MALAYSIA)
BAHAGIAN DASAR DAN HUBUNGAN ANTARABANGSA
(POLICY AND INTERNATIONAL RELATIONS DIVISION)
ARAS 6, 8 & 11, BLOK E7, KOMPLEKS E
PUSAT PENTADBIRAN KERAJAAN PERSEKUTUAN
62590 PUTRAJAYA

TEL : +603-8883 3888 (GL)
FAKS : +603-8883 2331 (L6)
: +603-8888 8692 (L8)
: +603-8883 2571 (L11)
URL : http://korporat.moh.gov.my

Ruj. Kami : (4) KKM 205/K/1 Jld. 4 s.k. 9
Tarikh : 8 Januari 2014

SEGERA DENGAN TANGAN

Ketua Pengarah
Unit Perancang Ekonomi
Jabatan Perdana Menteri
Blok B5 & B6
Pusat Pentadbiran Kerajaan Persekutuan
62502 PUTRAJAYA
(u.p : Puan Munirah binti Abd. Rahman)

Puan,

PERMOHONAN UNTUK MENJALANKAN KAJIAN DI MALAYSIA

Dengan segala hormatnya saya merujuk kepada perkara tersebut di atas. Surat puan rujukan UPE: 40/200/19/3075 bertarikh 18 Disember 2013 yang diterima pada 27 Disember 2013 adalah berkaitan.

2. Sukacita dimaklumkan bahawa Kementerian ini tiada halangan dengan permohonan daripada Puan Aniawanis Binti Makhtar untuk menjalankan penyelidikan yang bertajuk "*The Impact Of Diabetic Foot Ulcer Pain On Health-Related Quality of Life And Functional Status in Older Adults*". Kementerian ini berpandangan bahawa kajian tersebut memberi fokus kepada impak *Diabetic Foot Ulcer Pain* (DFUP) terhadap kualiti hidup dan kehidupan seharian pesakit diabetes dengan lebih teliti.

3. Selain itu, kajian ini dilihat dapat membantu menyumbang kepada peningkatan kepada kualiti perkhidmatan yang disampaikan di fasiliti kesihatan. Penyelidik tidak menyatakan lokasi/ nama hospital dan klinik kesihatan untuk kajian ini. Walau bagaimanapun, ia boleh dilaksanakan di mana-mana fasiliti KKM yang memberi rawatan kepada pesakit diabetes dan ia diharap tidak menggangu proses kerja dan perkhidmatan di klinik kesihatan atau hospital yang terpilih kelak.

4. Walau bagaimanapun, terdapat beberapa perkara yang perlu dipertimbangkan sebelum kajian tersebut diluluskan seperti berikut:

(i) Penyelidik memperoleh kelulusan etika dari pihak University of Cardiff;

(ii) Penyelidik perlu mendaftarkan penyelidikan ini di **National Medical Research Register** (NMRR). Pengecualian dari *Medical Research and Ethics Committee* (MREC) boleh dipohon dengan mengguna-pakai kelulusan etika dari University of Cardiff. Bagi maklumat lanjut, penyelidik boleh merujuk di laman sesawang www.nmrr.gov.my. ; dan

"Sila cantumkan rujukan surat ini apabila menjawab"

(iii) Sebarang bentuk penerbitan dan pembentangan hasil dari penyelidikan ini perlu mendapat **kelulusan Ketua Pengarah Kesihatan Malaysia**, selaras dengan Surat Pekeliling Ketua Pengarah Kesihatan Bil.1/2013 bertarikh 4 Januari 2013.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(LIM SHEAN LEE)
Bahagian Dasar dan Hubungan Antarabangsa
b.p. Ketua Setiausaha
Kementerian Kesihatan Malaysia

s.k. Pengarah
Bahagian Kawalan Penyakit
Kementerian Kesihatan Malaysia

Puan Aniawanis Binti Makhtar
16 Canton Court,
Canton, Cardiff,
CF11 9BG.
MakhtarA@cardiff.ac.uk

A 3.3: Ethical approval from Secondary Care Clinic 1

PERSETUJUAN PENYELIDIK, PENGESAHAN KETUA JABATAN DAN INSTITUSI

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Unique Research ID : *[Nombor Pendaftaran]*	19444
Research Title : *[Tajuk]*	The impact of diabetic foot ulcer pain on the health-related quality of life and functional status of elderly in Malaysia
Protocol Number if available : *[Nombor Protokol jika ada]*	

Investigator agreement ***[Persetujuan penyelidik]***

I have understood the above titled proposed research and I agree to participate in the research as an investigator.

Saya faham cadangan penyelidikan yang bertajuk di atas dan saya bersetuju mengambil bahagian dalam projek tersebut sebagai penyelidik.

Name of Investigator : *[Nama Penyelidik]*	ANIAWANIS BINTI MAKHTAR
IC number : *[Nombor KP]*	750209035582
Site Institution : *[Institusi]*	Kuala Lumpur Hospital
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	Ani
Date : *[Tarikh]*	22/5/2014.

Head of Department Agreement ***[Persetujuan Ketua Jabatan]***

I agree to allow the above named investigator to conduct or to participate in the above titled research.

Saya membenarkan pegawai yang bernama di atas untuk menjadi penyelidik dalam projek penyelidikan tersebut di atas.

Name of Head : *[Nama Ketua]*	Dr Ngau Yen Yew. DR. NGAU YEN YEW (Reg: 26541) M.D (USM).M.MED (UKM), MRCP(UK) PAKAR PERUNDING PERUBATAN KANAN KETUA JABATAN PERUBATAN HOSPITAL KUALA LUMPUR
Name of Department and Institution *[Jabatan dan Institusi]*	Dept of Medicine Hkl
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	
Date : *[Tarikh]*	22/5/2014.

Institutional approval ***[Pengesahan Institusi]***

This section maybe omitted if one of the NIH institute is authorized to approve on behalf of institution. Refer NIH for details.

[Bahagian ini tidak perlu jika salah satu daripada institusi NIH diberi kuasa pengesahan bagi pihak institusi tersebut. Rujuk NIH untuk maklumat lanjut]

I agree to allow the investigator(s) named above to conduct or to participate in the above titled research. Where applicable, I further agree to allow my institution to be one of the sites participating in the research.

Saya membenarkan pegawai yang bernama di atas menjalankan penyelidikan selaku penyelidik dalam projek penyelidikan tersebut. Jika berkenaan, saya juga membenarkan institusi ini mengambil bahagian dalam projek tersebut.

Name of Director : *[Nama Pengarah]*	DR. DING LAY MING (MPM: 27260) Timbalan Pengarah (Perubatan) II Pengurusan Hospital Kuala Lumpur
Name of Institution *[Institusi]*	
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	10/6/14

A 3.4: Ethical approval from Secondary Care Clinic 2

PERSETUJUAN PENYELIDIK, PENGESAHAN KETUA JABATAN DAN INSTITUSI

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Unique Research ID : *[Nombor Pendaftaran]*	19444
Research Title : *[Tajuk]*	The impact of diabetic foot ulcer pain on the health-related quality of life and functional status of elderly in Malaysia
Protocol Number if available : *[Nombor Protokol jika ada]*	

Investigator agreement ***[Persetujuan penyelidik]***

I have understood the above titled proposed research and I agree to participate in the research as an investigator.

Saya faham cadangan penyelidikan yang bertajuk di atas dan saya bersetuju mengambil bahagian dalam projek tersebut sebagai penyelidik.

Name of Investigator : *[Nama Penyelidik]*	ANIAWANIS BINTI MAKHTAR
IC number : *[Nombor KP]*	750209035582
Site Institution : *[Institusi]*	Kuala Lumpur Hospital
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	Ani
Date : *[Tarikh]*	22/5/2014

Head of Department Agreement ***[Persetujuan Ketua Jabatan]***

I agree to allow the above named investigator to conduct or to participate in the above titled research.

Saya membenarkan pegawai yang bernama di atas untuk menjadi penyelidik dalam projek penyelidikan tersebut di atas.

Name of Head : *[Nama Ketua]*	DR. ANANTHA RAJ DANIEL A/L JOSEPH THOMAS
Name of Department and Institution *[Jabatan dan Institusi]*	JABATAN PESAKIT LUAR
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	Dr Anantha Raj Daniel (A.M.N.) (MMC:26872) Ketua Jabatan Pesakit Luar Hospital Kuala Lumpur
Date : *[Tarikh]*	10/06/2014.

Institutional approval ***[Pengesahan Institusi]***

This section maybe omitted if one of the NIH institute is authorized to approve on behalf of institution. Refer NIH for details.

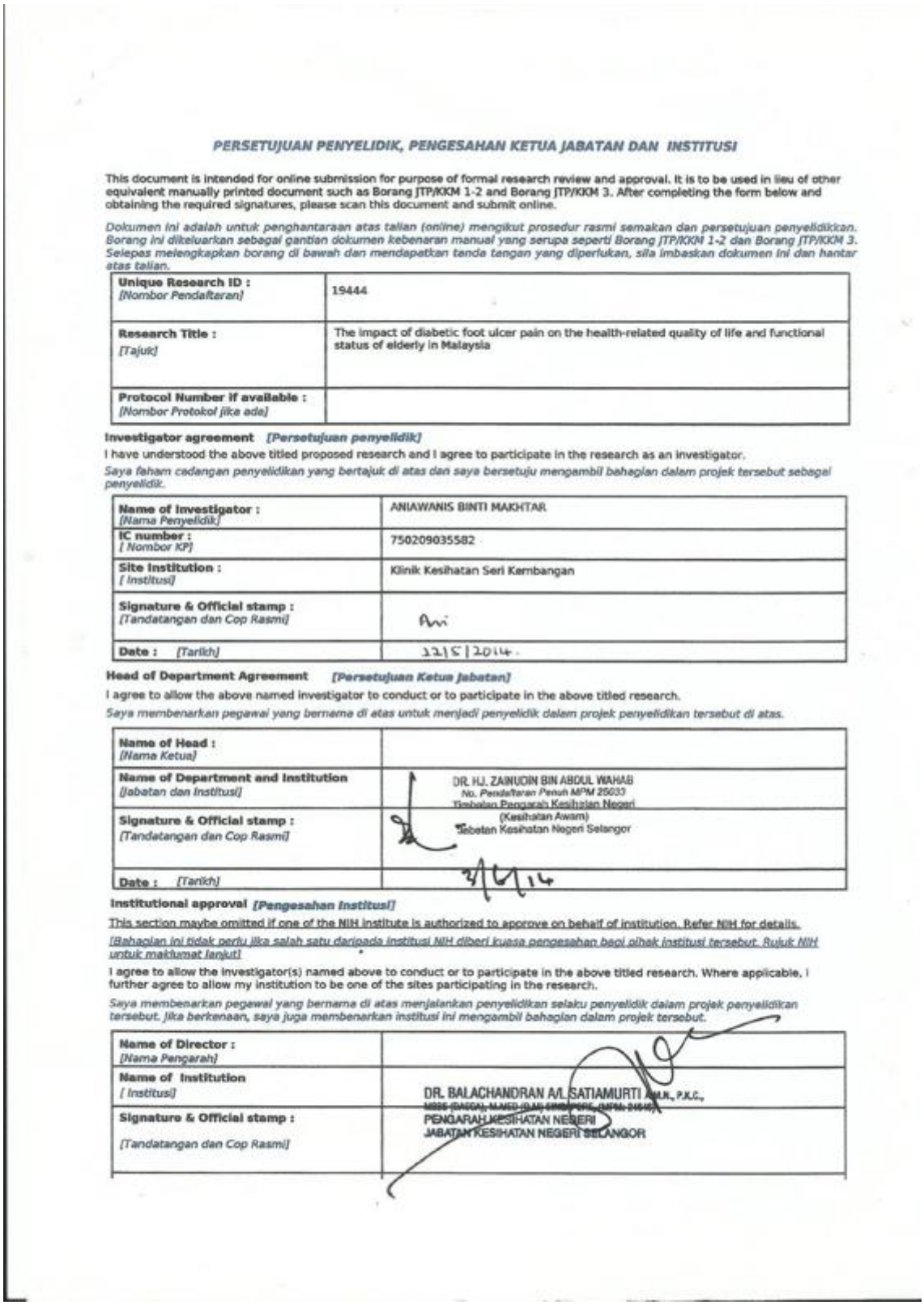
(Bahagian ini tidak perlu jika salah satu daripada institusi NIH diberi kuasa pengesahan bagi pihak institusi tersebut. Rujuk NIH untuk maklumat lanjut)

I agree to allow the investigator(s) named above to conduct or to participate in the above titled research. Where applicable, I further agree to allow my institution to be one of the sites participating in the research.

Saya membenarkan pegawai yang bernama di atas menjalankan penyelidikan selaku penyelidik dalam projek penyelidikan tersebut. Jika berkenaan, saya juga membenarkan institusi ini mengambil bahagian dalam projek tersebut.

Name of Director : *[Nama Pengarah]*	DR. DING LAY MING (MPM: 27200) Timbalan Pengarah (Perubatan) II b.p. Pengarah Hospital Kuala Lumpur
Name of Institution *[Institusi]*	
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	10/6/14

A 3.5: Ethical approval from Primary Care Clinic 1



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Unique Research ID : *[Nombor Pendaftaran]*	19444
Research Title : *[Tajuk]*	The impact of diabetic foot ulcer pain on the health-related quality of life and functional status of elderly in Malaysia
Protocol Number if available : *[Nombor Protokol jika ada]*	

Investigator agreement ***[Persetujuan penyelidik]***

I have understood the above titled proposed research and I agree to participate in the research as an investigator.

Saya faham cadangan penyelidikan yang bertajuk di atas dan saya bersetuju mengambil bahagian dalam projek tersebut sebagai penyelidik.

Name of Investigator : *[Nama Penyelidik]*	ANIAWANIS BINTI MAKHTAR
IC number : *[Nombor KP]*	750209035582
Site Institution : *[Institusi]*	Klinik Kesihatan Seri Kembangan
Signature & Official stamp : *(Tandatangan dan Cop Rasmi]*	Ani
Date : *[Tarikh]*	22/5/2014.

Head of Department Agreement ***[Persetujuan Ketua Jabatan]***

I agree to allow the above named investigator to conduct or to participate in the above titled research.

Saya membenarkan pegawai yang bernama di atas untuk menjadi penyelidik dalam projek penyelidikan tersebut di atas.

Name of Head : *[Nama Ketua]*	
Name of Department and Institution *[Jabatan dan Institusi]*	DR. HJ. ZAINUDIN BIN ABDUL WAHAB No. Pendaftaran Perubi MPM 25033 Timbalan Pengarah Kesihatan Negeri (Kesihatan Awam) Jabatan Kesihatan Negeri Selangor
Signature & Official stamp : *(Tandatangan dan Cop Rasmi]*	
Date : *[Tarikh]*	3/6/14

Institutional approval ***[Pengesahan Institusi]***

This section maybe omitted if one of the NIH institute is authorized to approve on behalf of institution. Refer NIH for details.

[Bahagian ini tidak perlu jika salah satu daripada institusi NIH diberi kuasa pengesahan bagi pihak institusi tersebut. Rujuk NIH untuk maklumat lanjut]

I agree to allow the investigator(s) named above to conduct or to participate in the above titled research. Where applicable, I further agree to allow my institution to be one of the sites participating in the research.

Saya membenarkan pegawai yang bernama di atas menjalankan penyelidikan selaku penyelidik dalam projek penyelidikan tersebut. Jika berkenaan, saya juga membenarkan institusi ini mengambil bahagian dalam projek tersebut.

Name of Director : *[Nama Pengarah]*	
Name of Institution *[Institusi]*	DR. BALACHANDRAN A/L SATIAMURTI [illegible] PENGARAH KESIHATAN NEGERI JABATAN KESIHATAN NEGERI SELANGOR
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	

A 3.6: Ethical approval from Primary Care Clinic 2

PERSETUJUAN PENYELIDIK, PENGESAHAN KETUA JABATAN DAN INSTITUSI

This document is intended for online submission for purpose of formal research review and approval. It is to be used in lieu of other equivalent manually printed document such as Borang JTP/KKM 1-2 and Borang JTP/KKM 3. After completing the form below and obtaining the required signatures, please scan this document and submit online.

Dokumen ini adalah untuk penghantaraan atas talian (online) mengikut prosedur rasmi semakan dan persetujuan penyelidikkan. Borang ini dikeluarkan sebagai gantian dokumen kebenaran manual yang serupa seperti Borang JTP/KKM 1-2 dan Borang JTP/KKM 3. Selepas melengkapkan borang di bawah dan mendapatkan tanda tangan yang diperlukan, sila imbaskan dokumen ini dan hantar atas talian.

Unique Research ID : *[Nombor Pendaftaran]*	19444
Research Title : *[Tajuk]*	The impact of diabetic foot ulcer pain on the health-related quality of life and functional status of elderly in Malaysia
Protocol Number if available : *[Nombor Protokol jika ada]*	

Investigator agreement ***[Persetujuan penyelidik]***

I have understood the above titled proposed research and I agree to participate in the research as an investigator.

Saya faham cadangan penyelidikan yang bertajuk di atas dan saya bersetuju mengambil bahagian dalam projek tersebut sebagai penyelidik.

Name of Investigator : *[Nama Penyelidik]*	ANIAWANIS BINTI MAKHTAR
IC number : *[Nombor KP]*	750209035582
Site Institution : *[Institusi]*	Klinik Kesihatan Jinjang
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	Ani
Date : *[Tarikh]*	22/5/2014

Head of Department Agreement ***[Persetujuan Ketua Jabatan]***

I agree to allow the above named investigator to conduct or to participate in the above titled research.

Saya membenarkan pegawai yang bernama di atas untuk menjadi penyelidik dalam projek penyelidikan tersebut di atas.

Name of Head : *[Nama Ketua]*	DR. UMMI KALTHOM BINTI SHAMSUDIN
Name of Department and Institution *[Jabatan dan Institusi]*	No. Pendaftaran MPM : 3433 Timbalan Pengarah Kesihatan Negeri Bahagian Kesihatan Awam Jabatan Kesihatan W.P Kuala Lumpur & Putrajaya
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	
Date : *[Tarikh]*	14/6/14

Institutional approval ***[Pengesahan Institusi]***

This section maybe omitted if one of the NIH institute is authorized to approve on behalf of institution. Refer NIH for details.

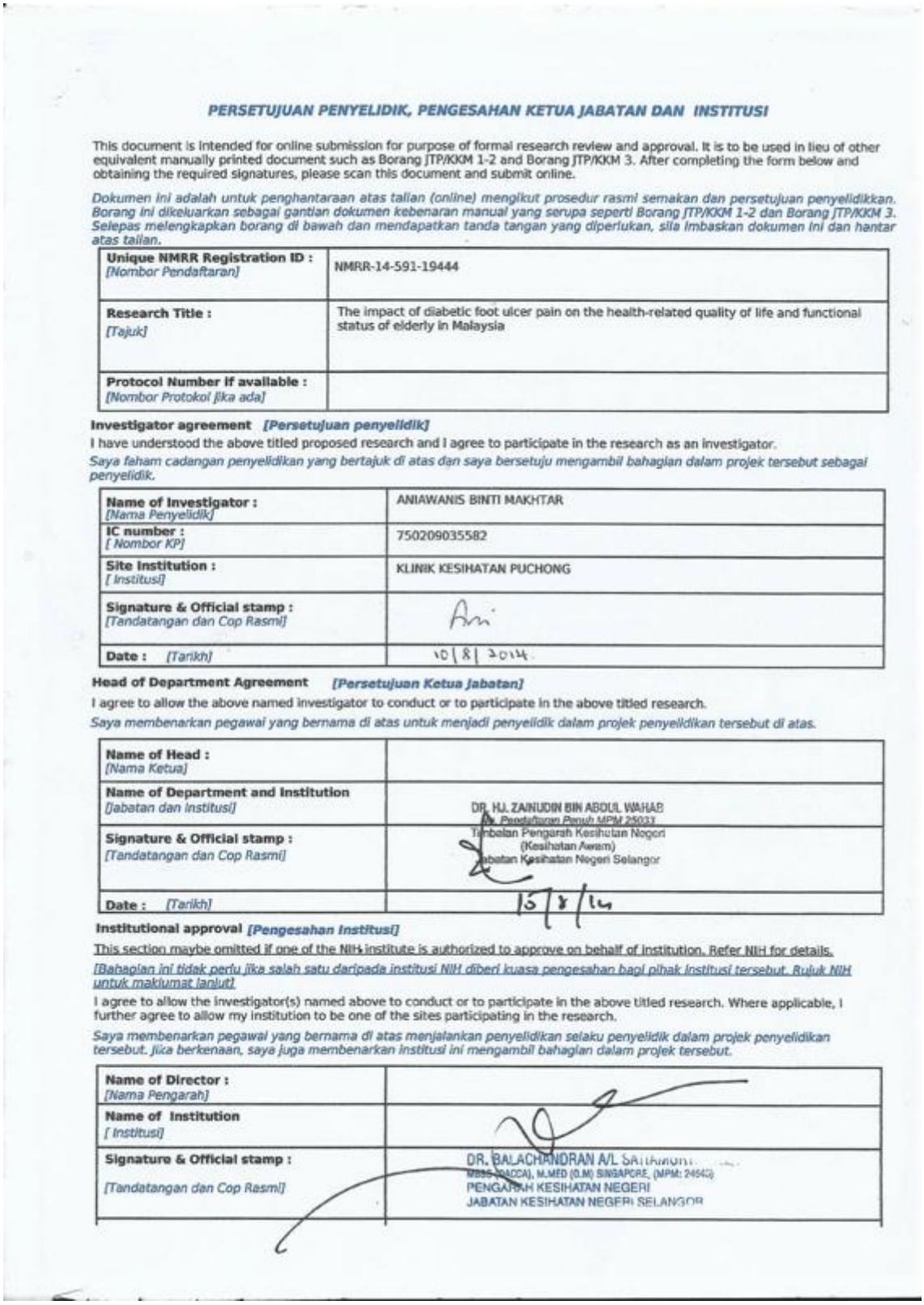
[Bahagian ini tidak perlu jika salah satu daripada institusi NIH diberi kuasa pengesahan bagi pihak institusi tersebut. Rujuk NIH untuk maklumat lanjut]

I agree to allow the investigator(s) named above to conduct or to participate in the above titled research. Where applicable, I further agree to allow my institution to be one of the sites participating in the research.

Saya membenarkan pegawai yang bernama di atas menjalankan penyelidikan selaku penyelidik dalam projek penyelidikan tersebut. Jika berkenaan, saya juga membenarkan institusi ini mengambil bahagian dalam projek tersebut.

Name of Director : *[Nama Pengarah]*	
Name of Institution *[Institusi]*	
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	DATUK DR. NARIMAH NOR BINTI YAHAYA No. Pendaftaran Perubatan MMC: 24528 Pengarah Kesihatan Negeri Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur & Putrajaya

A 3.7: Ethical approval from Primary Care Clinic 3



PERSETUJUAN PENYELIDIK, PENGESAHAN KETUA JABATAN DAN INSTITUSI

This document is intended for online submission for purpose of formal research review and approval. It is to be used in lieu of other equivalent manually printed document such as Borang JTP/KKM 1-2 and Borang JTP/KKM 3. After completing the form below and obtaining the required signatures, please scan this document and submit online.

Dokumen ini adalah untuk penghantaraan atas talian (online) mengikut prosedur rasmi semakan dan persetujuan penyelidikkan. Borang ini dikeluarkan sebagai gantian dokumen kebenaran manual yang serupa seperti Borang JTP/KKM 1-2 dan Borang JTP/KKM 3. Selepas melengkapkan borang di bawah dan mendapatkan tanda tangan yang diperlukan, sila imbaskan dokumen ini dan hantar atas talian.

Unique NMRR Registration ID : *[Nombor Pendaftaran]*	NMRR-14-591-19444
Research Title : *[Tajuk]*	The impact of diabetic foot ulcer pain on the health-related quality of life and functional status of elderly in Malaysia
Protocol Number if available : *[Nombor Protokol jika ada]*	

Investigator agreement ***[Persetujuan penyelidik]***

I have understood the above titled proposed research and I agree to participate in the research as an investigator.

Saya faham cadangan penyelidikan yang bertajuk di atas dan saya bersetuju mengambil bahagian dalam projek tersebut sebagai penyelidik.

Name of Investigator : *[Nama Penyelidik]*	ANIAWANIS BINTI MAKHTAR
IC number : *[Nombor KP]*	750209035582
Site Institution : *[Institusi]*	KLINIK KESIHATAN PUCHONG
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	Ani
Date : *[Tarikh]*	10/8/2014

Head of Department Agreement ***[Persetujuan Ketua Jabatan]***

I agree to allow the above named investigator to conduct or to participate in the above titled research.

Saya membenarkan pegawai yang bernama di atas untuk menjadi penyelidik dalam projek penyelidikan tersebut di atas.

Name of Head : *[Nama Ketua]*	
Name of Department and Institution *[Jabatan dan Institusi]*	DR. HJ. ZAINUDIN BIN ABDUL WAHAB No. Pendaftaran Penuh MPM 25033 Timbalan Pengarah Kesihatan Negeri (Kesihatan Awam) Jabatan Kesihatan Negeri Selangor
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	
Date : *[Tarikh]*	15/8/14

Institutional approval ***[Pengesahan Institusi]***

This section maybe omitted if one of the NIH institute is authorized to approve on behalf of institution. Refer NIH for details.

[Bahagian ini tidak perlu jika salah satu daripada institusi NIH diberi kuasa pengesahan bagi pihak institusi tersebut. Rujuk NIH untuk maklumat lanjut]

I agree to allow the investigator(s) named above to conduct or to participate in the above titled research. Where applicable, I further agree to allow my institution to be one of the sites participating in the research.

Saya membenarkan pegawai yang bernama di atas menjalankan penyelidikan selaku penyelidik dalam projek penyelidikan tersebut. Jika berkenaan, saya juga membenarkan institusi ini mengambil bahagian dalam projek tersebut.

Name of Director : *[Nama Pengarah]*	
Name of Institution *[Institusi]*	
Signature & Official stamp : *[Tandatangan dan Cop Rasmi]*	DR. BALACHANDRAN A/L SATHAYAH MBBS (NAGPUR), M.MED (O&G) SINGAPORE, (MPM: 24642) PENGARAH KESIHATAN NEGERI JABATAN KESIHATAN NEGERI SELANGOR

A 3.8: Ethical approval from Malaysia Medical Research and Ethic Committee (MREC)

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur
Tel : 03 2282 0491
Faks : 03 2282 8072 / 03 2282 0015

Ruj. Kami : (5)KKM/NIHSEC/P14-989
Tarikh : 15 Oktober 2014

Aniawanis Binti Makhtar
Cardiff University School of Healthcare Sciences
College of Biomedical and Life Sciences

Puan,

NMRR-14-591-19444
The impact of diabetic foot ulcer pain on the health-related quality of life and functional status of elderly in Malaysia

Lokasi Projek: Hospital Kuala Lumpur/ Klinik Kesihatan Jinjang/ Klinik Kesihatan Puchong/ Klinik Kesihatan Seri Kembangan

Dengan hormatnya perkara di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia (KKM) mengambil maklum bahawa projek tersebut adalah untuk memenuhi keperluan akademik program Ijazah Doktor Falsafah Kejururawatan, Cardiff University , United Kingdom.

3. Sehubungan dengan ini, dimaklumkan bahawa pihak JEPP KKM tiada halangan, dari segi etika, ke atas pelaksanaan projek tersebut. JEPP mengambil maklum bahawa kajian ini tidak melibatkan sebarang intervensi terhadap subjek dan hanya melibatkan soal selidik dalam pengumpulan data kajian. Segala rekod dan data adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta prosedur mengenai ***data confidentiality*** mesti dipatuhi. Kebenaran daripada Pengarah Hospital/ Jabatan Kesihatan Negeri di mana kajian akan dijalankan mesti diperolehi terlebih dahulu sebelum kajian dijalankan. Puan perlu akur dan mematuhi keputusan tersebut.

4. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga 15 Oktober 2015. Puan perlu menghantar '*Continuing Review Form*' selewat-lewatnya 2 bulan sebelum tamat tempoh kelulusan ini bagi memperbaharui kelulusan etika. Pihak Puan juga perlu mengemukakan laporan tamat kajian dan juga laporan mengenai "*All adverse events, both serious and unexpected*" kepada Jawatankuasa Etika & Penyelidikan Perubatan, KKM jika berkenaan. Borang-borang berkaitan boleh dimuat turun daripada laman web MREC (http://www.nih.gov.my/mrec)

Sekian terima kasih.

BERKHIDMAT UNTUK NEGARA

Saya yang menurut perintah,

(DATO' DR CHANG KIAN MENG)
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia

Sk : Pengarah Hospital Kuala Lumpur
Pengarah Jabatan Kesihatan Negeri
CRC Hospital Kuala Lumpur

Appendix 4: Study Document

A 4.1: The English version of the questionnaire

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Participant code: .....

Title of project: The impact of diabetic foot ulcer pain on the health-related quality of life and functional status of older people in Malaysia.

Instructions to participant:
Please answer all questions
Thank you

Section one: Demographic Data
Read each question and answer it, please indicate your answer by placing a cross (X) in the appropriate box or providing the information in the blank spaces.

Q1. Age ..... (in years)

Q2. Gender
- Male ☐
- Female ☐

Q3. Race
- Malay ☐
- Chinese ☐
- India ☐
- Other ☐

Q4. Religion
- Muslim ☐
- Buddhist ☐
- Hindu ☐
- Christian ☐
- Other ☐
- No religion ☐

Q5. Marital Status
- Single ☐
- Married ☐
- Divorced ☐
- Widowed ☐
- Separated ☐

Q6. Educational level

- Never ☐
- Primary education ☐
- Secondary education ☐
- Tertiary education ☐

Q7. Number of storey

- 1 storey ☐
- 1 ½ storey ☐
- 2 storey ☐
- 2 ½ storey ☐
- 3 storey and above ☐

Section two: Clinical Data and Utilisation of Health Services
Read each question and answer it, please indicate your answer by placing a cross (X) or circle in the appropriate box or providing the information in the blank spaces.

Q1. Duration of diabetes ..... (Approximate/Actual)

Q2. Types of diabetes treatment

Diet control	☐
Oral hypoglycaemic agents (OHA)	☐
Insulin therapy	☐
Both insulin and OHA	☐

Q3. Number of other co-morbodities besides diabetes, present at the time of study

0	☐
1	☐
2	☐
≥3	☐

Q4. Foot ulcer episode

1st episode	☐
2nd episode	☐
3rd episode	☐
More than three times	☐

Q5. Duration of foot ulcer: ..... (Approximate/Actual)

Q6. Site of foot ulcer

- Forefoot ☐
- Midfoot ☐
- Hindfoot ☐

Q7. Wagner wound classification

Grade 0	☐	Grade 3	☐
Grade 1	☐	Grade 4	☐
Grade 2	☐	Grade 5	☐

Q8. The cause of diabetic foot ulcer

- Improperly fitting foot wear ☐
- Injury ☐
- Burns ☐
- Foot deformity ☐
- Spontaneous blisters ☐
- Fungal infection ☐
- No evidence of cause ☐

Q9. Frequency of dressing change

- Daily ☐
- Twice a day ☐
- Others please specify ..... ☐

Q10. Type of cleaning solution

- Saline ☐
- Sterile water ☐
- Others please specify ..... ☐

Q11. Type of dressing

Dry gauze	☐	Foam	☐
Saline soaked (wet to dry) dressing	☐	Calcium alginates	☐
Antimicrobials	☐	Hydrocolloid	☐
Gel dressing	☐	Others please specify	☐

Q12. Treatment related instruction/method

Total contact cast	☐	Foot rest	☐
Back slab	☐	Elevation of limb	☐
Orthosis	☐	Restriction of mobility level	☐
Sandal	☐	Non-weight bearing walking with crutches	☐
Insole	☐	Others, please specify	☐

Q13. History of related operations

None	☐	Ray amputation	☐
Debridement	☐	Forefoot amputation	☐
Skin graft	☐	Below knee amputation	☐
Toe amputation	☐	Above knee amputation	☐

Q14. Do you take pain relief for your pain?

Yes ☐

No ☐

Q15. Does medication relieve your pain?

Yes ☐

No ☐

Q16. How much verbal information about wound pain control have you received?

Circle one

A lot.....1
Some 2
A little.....3
None.....4

Q17. How much written information about wound pain control have you received?

	Circle one
A lot	1
Some	2
A little	3
None	4

Q18. Who have you received information from about wound pain control?

- Nurse ☐
- Doctor ☐
- Other healthcare person (please describe) ..... ☐
- Family / Friends ☐
- Internet ☐
- Others ☐
- No one ☐

Q19. How satisfied have you been so far with the care of your wound has received in the health care clinic?

	Circle one
Very satisfied	1
Satisfied	2
Somewhat satisfied	3
Somewhat unsatisfied	4
Unsatisfied	5
Very unsatisfied	6

Q20. Do you have any comments or suggestions to improve the quality of health services at the clinic?

.....
.....
.....
.....
.....
.....
.....

Section three: The Medical Outcome Study Short Form 36 (SF-36)
This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. **In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **Compared to one year ago, how would you rate your health in general now?**

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. **The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?**

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b	Moderate activities, such as moving a table, sweeping, playing badminton, or gardening	☐ 1	☐ 2	☐ 3
c	Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d	Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e	Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f	Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g	Walking more than a kilometre	☐ 1	☐ 2	☐ 3
h	Walking several hundred metres	☐ 1	☐ 2	☐ 3
i	Walking one hundred metres	☐ 1	☐ 2	☐ 3
j	Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. **During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. **During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **How much bodily pain have you had during the past 4 weeks?**

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so sad and low in mood that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. **How TRUE or FALSE is each of the following statements for you?**

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

TOTAL POINTS:

Section four: Diabetic Foot Ulcer Scale- Short Form (DFS-SF)
These questions are related to the possible impact of a diabetic foot ulcer on your daily life and health. Please read question carefully and estimate the impact of a diabetic foot ulcer on you. When answering, each question, please circle only one number.
Please circle the one that you think will most fit.

Q1. How much have your foot ulcer problems:	Not at all	A little bit	Moderately	Quite a bit	A great deal
a. Stopped you from doing the hobbies and recreational activities that you enjoy	1	2	3	4	5
b. Changed the kinds of hobbies and recreational activities that you enjoy doing.	1	2	3	4	5
c. Stopped you from getting away for a holiday or a weekend break.	1	2	3	4	5
d. Made you choose a different kind of holiday or short break than you would have preferred.	1	2	3	4	5
e. Meant that you had to spend more time planning and organising for leisure activities.	1	2	3	4	5

Q2. Because of your foot problems, how often have you felt	None of the time	A little of the time	Some of the time	Most of the time	All the time
a. fatigue or tired	1	2	3	4	5
b. drained	1	2	3	4	5
c. that you had difficulty sleeping	1	2	3	4	5
d. pain while walking or standing	1	2	3	4	5
e. pain during the night	1	2	3	4	5

Q3. Because of your foot ulcer problems, how often have you	None of the time	A little of the time	Some of the time	Most of the time	All the time
a. had depend on others to help you look after yourself(such as washing and dressing yourself)	1	2	3	4	5
b. had to depend on others to do household chores such as cooking, cleaning or laundry	1	2	3	4	5
c. had to depend on others to get out of the house	1	2	3	4	5
d. had to spend more time planning or organising your daily life	1	2	3	4	5
e. felt that doing anything took longer than you would have liked	1	2	3	4	5

Q4. Because of your foot ulcer problems, how often have you	Not at all	Slight-ly	Moderately	Quite a bit	Extre-mely
a. angry because you were not able to do what you wanted to do	1	2	3	4	5
b. frustrated by others doing things for you when you would rather do things yourself	1	2	3	4	5
c. frustrated because you were not able to do what you wanted to do	1	2	3	4	5
d. worried that your ulcer(s) will never heal	1	2	3	4	5
e. worried that you may have to have a amputation	1	2	3	4	5
f. worried about injury to your feet	1	2	3	4	5
g. depressed because you were not able to do what you wanted to do	1	2	3	4	5
h. worried about getting ulcers in the future	1	2	3	4	5
i. angry that this has happened to you	1	2	3	4	5
j. frustrated because you have difficulty in getting about	1	2	3	4	5

Q5. Because of your foot ulcer problems, how often were you bothered by:	Not at all	Slight-ly	Moderately	Quite a bit	Extre-mely
a. having to keep the weight off your foot ulcer	1	2	3	4	5
b. the amount of time involved in caring for your foot ulcer (including dressing changes, waiting for the district nurse and keeping the ulcer clean)	1	2	3	4	5
c. the appearance, odour or leaking of your ulcer	1	2	3	4	5
d. having to depend on others to help you care for your foot ulcer	1	2	3	4	5

TOTAL POINTS:

Section five: Short-Form McGill Pain Questionnaire (SF-MPQ) Form X

3 □ **Not Done**

A. PLEASE DESCRIBE YOUR PAIN DURING THE LAST WEEK. *(✓ one box on each line.)*

	None	Mild	Moderate	Severe
1. Throbbing	0□	1□	2□	3□
2. Shooting	0□	1□	2□	3□
3. Stabbing	0□	1□	2□	3□
4. Sharp	0□	1□	2□	3□
5. Cramping	0□	1□	2□	3□
6. Gnawing	0□	1□	2□	3□
7. Hot-burning	0□	1□	2□	3□
8. Aching	0□	1□	2□	3□
9. Heavy	0□	1□	2□	3□
10. Tender	0□	1□	2□	3□
11. Splitting	0□	1□	2□	3□
12. Tiring-exhausting	0□	1□	2□	3□
13. Sickening	0□	1□	2□	3□
14. Fearful	0□	1□	2□	3□
15. Punishing-cruel	0□	1□	2□	3□

B. RATE YOUR PAIN DURING THE PAST WEEK

The following line represents pain of increasing intensity from "no pain" to "worst possible pain". Place a slash (|) across the line in the position that best describes your pain **during the past week.**

No pain **Worst possible pain**

□□□

Score in mm
(Investigator's use only)

C. PRESENT PAIN INTENSITY

0 □ No pain
1 □ Mild
2 □ Discomforting
3 □ Distressing
4 □ Horrible
5 □ Excruciating

Section six: Katz Index of Independence in Activities of Daily Living (ADL)

ACTIVITIES Points (1 or 0)	**INDEPENDENCE: (1 POINT)** NO supervision, direction or personal assistance	**DEPENDENCE: (0 POINTS)** WITH supervision, direction, personal assistance or total care
BATHING POINTS: ___	(1 POINT) Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	(0 POINTS) Needs help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.
DRESSING POINTS: ___	(1 POINT) Gets clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	(0 POINTS) Needs help with dressing self or needs to be completely dressed.
TOILETING POINTS: ___	(1 POINT) Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	(0 POINTS) Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
TRANSFERRING POINTS: ___	(1 POINT) Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable.	(0 POINTS) Needs help in moving from bed to chair or requires a complete transfer.
CONTINENCE POINTS: ___	(1 POINT) Exercises complete self control over urination and defecation.	(0 POINTS) Is partially or totally incontinent of bowel or bladder.
FEEDING POINTS: ___	(1 POINT) Gets food from plate into mouth without help. Preparation of food may be done by another person.	(0 POINTS) Needs partial or total help with feeding or requires parenteral feeding.

TOTAL POINTS: _____

Section seven: Lawton Instrumental Activities of Daily Living (IADL) Scale
The following questions are about your independence activity daily living. Read each question and answer it, making a circle at a number.

A. Ability to Use Telephone	
1. Operates telephone on own initiative; looks up and dials numbers	1
2. Dials a few well-known numbers	1
3. Answers telephone, but does not dial	1
4. Does not use telephone at all	0

B. Shopping	
1. Takes care of all shopping needs independently	1
2. Shops independently for small purchases	0
3. Needs to be accompanied on any shopping trip	0
4. Completely unable to shop	0

C. Food Preparation	
1. Plans, prepares, and serves adequate meals independently	1
2. Prepares adequate meals if supplied with ingredients	0
3. Heats and serves prepared meals or prepares meals but does not maintain adequate diet	0
4. Needs to have meals prepared and served	0

D. Housekeeping	
1. Maintains house alone with occasion assistance (heavy work)	1
2. Performs light daily tasks such as dishwashing, bed making	1
3. Performs light daily tasks, but cannot maintain acceptable level of cleanliness	1
4. Needs help with all home maintenance tasks	1
5. Does not participate in any housekeeping tasks	0

E. Laundry	
1. Does personal laundry completely	1
2. Launders small items, rinses socks, stockings, etc.	1
3. All laundry must be done by others	0

F. Mode of Transportation	
1. Travels independently on public transportation or drives own car	1
2. Arranges own travel via taxi, but does not otherwise use public transportation	1
3. Travels on public transportation when assisted or accompanied by another	1
4. Travel limited to taxi or automobile with assistance of another	0
5. Does not travel at all	0

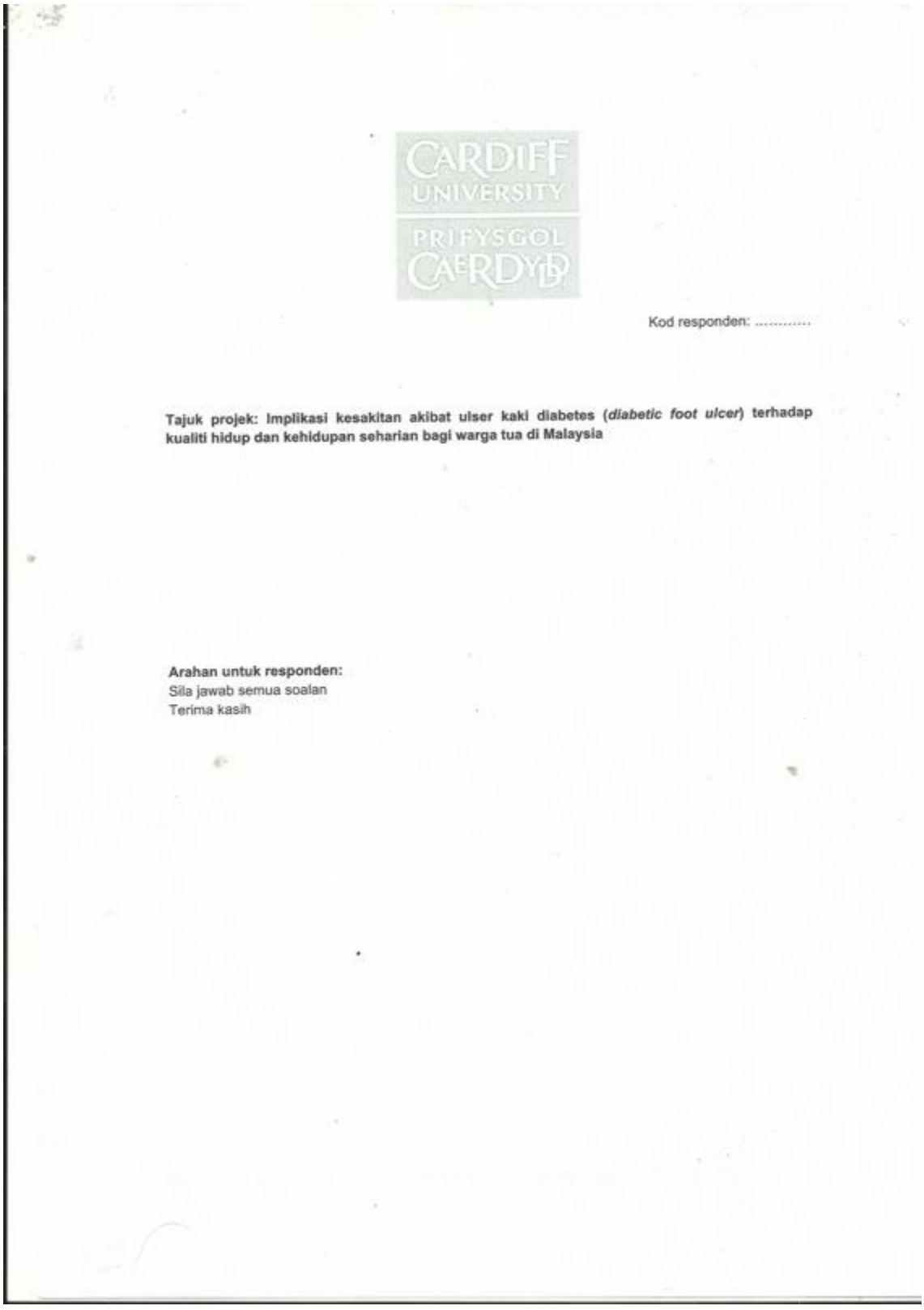
G. Responsibility for Own Medications	
1. Is responsible for taking medication in correct dosages at correct time	1
2. Takes responsibility if medication is prepared in advance in separate dosages	0
3. Is not capable of dispensing own medication	0

H. Ability to Handle Finances	
1. Manages financial matters independently (budgets, writes checks, pays rent and bills, goes to bank); collects and keeps track of income	1
2. Manages day-to-day purchases, but needs help with banking, major purchases, etc	1
3. Incapable of handling money	0

TOTAL POINTS: _____

Thank you very much for your kind cooperation

A 4.2: The Malay version of the questionnaire



CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Kod responden: .....

Tajuk projek: Implikasi kesakitan akibat ulser kaki diabetes (*diabetic foot ulcer*) terhadap kualiti hidup dan kehidupan seharian bagi warga tua di Malaysia

Arahan untuk responden:
Sila jawab semua soalan
Terima kasih

Bahagian satu: Maklumat Demografi
Sila baca setiap soalan dan berikan jawapan anda dengan menanda pangkah (X) di dalam kotak yang disediakan atau mengisi jawapan yang paling sesuai dengan diri anda.

Q1. Umur ..... (dalam tahun)

Q2. Jantina
- Lelaki ☐
- Wanita ☐

Q3. Bangsa
- Melayu ☐
- Cina ☐
- India ☐
- Lain-lain ☐

Q4. Agama
- Islam ☐
- Buddha ☐
- Hindu ☐
- Kristian ☐
- Lain-lain ☐
- Tiada agama ☐

Q5. Taraf Perkahwinan
- Bujang ☐
- Berkahwin ☐
- Bercerai ☐
- Janda/Duda ☐
- Berpisah ☐

Q6. Taraf Pendidikan

Tidak pernah sekolah	☐
Rendah	☐
Menengah	☐
Kolej/Universiti	☐

Q7. Bilangan Tingkat

1 tingkat	☐
1 ½ tingkat	☐
2 tingkat	☐
2 ½ tingkat	☐
3 tingkat ke atas	☐

Bahagian dua: Data Klinikal dan Penggunaan Kemudahan Kesihatan
Sila baca setiap soalan dan berikan jawapan anda dengan menanda pangkah (X) atau bulatkan jawapan anda atau tulis jawapan anda di ruang yang disediakan.

Q1. Jangkamasa menghidapi diabetes/ Kencing Manis..... (Anggaran/Tepat)

Q2. Jenis Rawatan Diabetes/ Kencing Manis

Kawalan diet	☐
Oral hypoglycaemic agents (OHA)	☐
Terapi Insulin	☐
Insulin dan OHA	☐

Q3. Jumlah penyakit lain yang dihidapi ketika ini selain diabetes/ kencing manis.

0	☐
1	☐
2	☐
≥3	☐

Q4. Episod ulser kaki

Kali pertama	☐
Kali kedua	☐
Kali ketiga	☐
Lebih daripada tiga kali	☐

Q5. Jangkamasa menghidapi ulser kaki: ..... (Anggaran/Tepat)

Q6. Bahagian yang mengalami ulser kaki

Kaki hadapan	☐
Tengah kaki	☐
Belakang kaki	☐

Q7. Klasifikasi ulser kaki mengikut tahap Wagner

Tahap 0	☐	Tahap 3	☐
Tahap 1	☐	Tahap 4	☐
Tahap 2	☐	Tahap 5	☐

Q8. Penyebab kepada ulser kaki

- Pemakaian kasut yang tidak betul ☐
- Kecederaan ☐
- Terbakar ☐
- Kecacatan kaki ☐
- Melepuh/mengelembung secara spontan ☐
- Fungal infection ☐
- Tiada penyebab yang nyata ☐

Q9. Kekerapan menukar balutan

- Setiap hari ☐
- Dua kali sehari ☐
- Lain-lain, sila nyatakan ..... ☐

Q10. Jenis larutan pencuci

- Air garam ☐
- Air steril ☐
- Lain-lain, sila nyatakan ..... ☐

Q11. Jenis balutan

Dry gauze	☐	Foam	☐
Saline soaked (wet to dry) dressing	☐	Calcium alginates	☐
		Hydrocolloid	☐
Antimicrobials	☐	Lain-lain, sila nyatakan	☐
Gel dressing	☐		

Q12. Arahan/kaedah rawatan

Simen (*Total contact cast*)	☐	Rehatkan kaki	☐
Back slab	☐	Menaikkan aras kaki	☐
Orthosis	☐	Menghadkan pergerakan	☐
Sandal	☐	Bergerak menggunakan tongkat	☐
Insole	☐	Lain-lain, sila nyatakan	☐

Q13. Sejarah pembedahan akibat diabetes/ kencing manis

Tiada	☐	Ray amputation	☐
Pembuangan tisu mati	☐	Amputasi kaki hadapan	☐
Tampalan kulit	☐	Amputasi bawah lutut	☐
Amputasi ibu jari	☐	Amputasi atas lutut	☐

Q14. Adakah anda mengambil ubat tahan sakit?

Ya ☐

Tidak ☐

Q15. Adakah ubat-ubatan mengurangkan kesakitan anda?

Ya ☐

Tidak ☐

Q16. Berapa banyak maklumat tentang kawalan kesakitan akibat luka yang telah anda terima secara lisan?

Bulatkan satu

Banyak.....1
Beberapa 2
Sedikit.....3
Tiada.....4

Q17. Berapa banyak maklumat tentang kawalan kesakitan akibat luka yang telah anda terima secara bertulis?

Bulatkan satu

Banyak.....1
Beberapa 2
Sedikit.....3
Tiada.....4

Q18. Nyatakan apakah sumber-sumberanda memperolehi maklumat tentang kawalan kesakitan akibat luka?

Jururawat ☐

Doktor ☐

Pengamal kesihatan lain (sila nyatakan) ..... ☐

Keluarga / rakan-rakan ☐

Internet ☐

Lain-lain ☐

Tiada ☐

Q19. Adakah anda berpuashati dengan rawatan yang telah diterima di klinik perubatan untuk luka anda?

Bulatkan satu

Sangat berpuashati..... 1

Puashati 2

Sedikit puashati..... 3

Sedikit tidak berpuashati..... 4

Tidak berpuashati..... 5

Sangat tidak berpuashati..... 6

Q20. Adakah anda mempunyai sebarang komen atau cadangan untuk memperbaiki kualiti perkhidmatan kesihatan di klinik-klinik?

.....
.....
.....
.....
.....
.....
.....

Bahagian tiga: The Medical Outcome Study Short Form 36 (SF-36)
Tinjauan ini meminta pandangan anda mengenai kesihatan anda. Maklumat ini akan memantau keadaan anda dan betapa baiknya anda dapat melakukan aktiviti anda yang biasa. *Terima kasih kerana melengkapkan tinjauan ini!*

Untuk setiap soalan berikut, sila tandakan ☒ di dalam satu kotak yang paling baik menerangkan jawapan anda.

1. **Secara umum, adakah anda akan mengatakan bahawa kesihatan anda adalah:**

Paling baik	Sungguh baik	Baik	Sederhana	Tidak baik
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **Berbanding dengan setahun yang lalu, bagaimanakah anda menilai kesihatan anda secara umum sekarang?**

Jauh lebih baik sekarang daripada setahun yang lalu	Agak lebih baik sekarang daripada setahun yang lalu	Lebih kurang sama dengan setahun yang lalu	Agak lebih teruk sekarang daripada setahun yang lalu	Jauh lebih teruk sekarang daripada setahun yang lalu
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. **Soalan-soalan berikut adalah mengenai aktiviti yang mungkin akan anda lakukan pada hari biasa. Adakah anda terbatas dalam sebarang aktiviti berikut kerana keadaan kesihatan anda sekarang? Jika ya, sejauh mana?**

	Ya, terbatas dengan banyaknya	Ya, terbatas dengan sedikitnya	Tidak, tidak terbatas sama sekali
a Aktiviti yang bertenaga dan sihat, seperti berlari, mengangkat barang berat, menyertai sukan yang memerlukan tenaga dan kekuatan	☐ 1	☐ 2	☐ 3
b Aktiviti sederhana, seperti mengalihkan meja, menyapu, bermain badminton atau bercucuk tanam	☐ 1	☐ 2	☐ 3
c Mengangkat atau membawa barang-barang runcit	☐ 1	☐ 2	☐ 3
d Menaiki beberapa larian tangga	☐ 1	☐ 2	☐ 3
e Menaiki satu larian tangga	☐ 1	☐ 2	☐ 3
f Membengkok, melutut atau membongkok	☐ 1	☐ 2	☐ 3
g Berjalan lebih daripada satu kilometer	☐ 1	☐ 2	☐ 3
h Berjalan beberapa ratus meter	☐ 1	☐ 2	☐ 3
i Berjalan seratus meter	☐ 1	☐ 2	☐ 3
j Mandi atau memakai pakaian sendiri	☐ 1	☐ 2	☐ 3

4. **Dalam masa 4 minggu yang lalu, berapa kerapkah anda mengalami sebarang masalah berikut apabila anda bekerja atau melakukan aktiviti harian tetap anda yang lain akibat kesihatan fizikal anda?**

	Setiap masa	Kebanyakan masa	Kadangkala	Sedikit masa	Tiada sama sekali
a Mengurangkan jumlah masa yang anda habiskan untuk bekerja atau melakukan aktiviti lain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Mencapai kurang daripada yang anda ingini	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Terbatas dari segi jenis pekerjaan atau aktiviti lain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Mempunyai kesukaran bekerja atau melakukan aktiviti lain (misalnya, memerlukan usaha yang lebih)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. **Dalam masa 4 minggu yang lalu, berapa kerapkah anda mengalami sebarang masalah berikut apabila anda bekerja atau melakukan aktiviti harian tetap anda yang lain akibat sebarang masalah emosi (seperti berasa murung atau bimbang)?**

	Setiap masa	Kebanyakan masa	Kadangkala	Sedikit masa	Tiada sama sekali
a Mengurangkan jumlah masa yang anda habiskan untuk bekerja atau melakukan aktiviti lain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Mencapai kurang daripada yang anda ingini	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Bekerja atau melakukan aktiviti lain dengan kurang berhati-hati daripada biasa	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **Dalam masa 4 minggu yang lalu, sejauh manakah kesihatan fizikal atau masalah emosi mengganggu aktiviti sosial biasa anda bersama keluarga, sahabat handai, jiran tetangga atau kumpulan?**

Tidak sama sekali	Sedikit	Sederhana	Agak banyak	Amat sangat
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **Dalam masa 4 minggu yang lalu, berapa banyakkah kesakitan yang anda alami?**

Tiada	Sedikit sangat	Sedikit	Banyak	Agak Banyak	Sungguh Banyak
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **Dalam masa 4 minggu yang lalu, sejauh manakah kesakitan telah mengganggu pekerjaan biasa anda (termasuk pekerjaan di luar rumah dan kerja rumah)?**

Tidak sama sekali	Sedikit	Sederhana	Agak banyak	Amat sangat
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. **Soalan-soalan ini adalah mengenai perasaan dan keadaan anda dalam masa 4 minggu yang lalu. Untuk setiap soalan, sila berikan satu jawapan yang paling hampir dengan keadaan perasaan anda. Dalam masa 4 minggu yang lalu, berapa kerapkah...**

	Setiap masa	Kebanyakan masa	Kadangkala	Sedikit masa	Tiada sama sekali
a Adakah anda berasa penuh bersemangat?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Pernahkah anda berasa sungguh gementar?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Pernahkah anda berasa sungguh sedih hinggakan tiada apa pun yang dapat menceriakan anda?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Pernahkah anda berasa tenang dan aman?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Adakah anda sungguh bertenaga?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Pernahkah anda berasa sedih dan murung?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Adakah anda berasa sangat letih?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Pernahkah anda berasa gembira?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Adakah anda berasa letih?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. **Dalam masa 4 minggu yang lalu, berapa kerapkah kesihatan fizikal atau masalah emosi telah mengganggu aktiviti sosial anda (seperti melawat sahabat handai, sanak saudara, dll.)?**

Setiap masa	Kebanyakan masa	Kadangkala	Sedikit masa	Tiada sama sekali
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. **Sejauh manakah <u>setiap</u> penyataan berikut BENAR atau TIDAK BENAR untuk anda?**

	Sungguh benar	Kebanyakannya benar	Tidak tahu	Kebanyakannya tidak benar	Sungguh tidak benar
a Saya kelihatan lebih mudah jatuh sakit daripada orang lain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Saya sihat seperti orang lain yang saya kenali	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Saya menjangkakan kesihatan saya akan menjadi lebih teruk	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Kesihatan saya adalah sungguh baik	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Bahagian empat: Diabetic Foot Ulcer Scale- Short Form (DFS-SF)
Semua soalan ini berkaitan dengan kesan ulser kaki diabetes yang mungkin memberi impak kepada kehidupan harian dan kesihatan anda.
Sila baca soalan dengan cermat dan beri anggaran kesan penyakit tersebut kepada anda. Apabila menjawab setiap barisan soalan, sila bulatkan SATU nombor sahaja yang anda rasakan paling hampir kesannya.

1. Sejauh manakah penyakit ulser kaki anda telah:

	Tidak Sama sekali	Sedikit	Sederhana	Agak banyak	Amat banyak
a) Menghalang anda daripada melakukan hobi atau aktiviti rekreasi yang anda gemar.	1	2	3	4	5
b) Mengubah jenis hobi dan aktiviti rekreasi yang anda gemari.	1	2	3	4	5
c) Membantutkan hasrat anda untuk pergi melancong atau bercuti hujung minggu.	1	2	3	4	5
d) Menyebabkan anda terpaksa memilih percutian atau percutian pendek yang lain daripada kegemaran biasa anda.	1	2	3	4	5
e) Membuatkan anda perlu meluangkan lebih masa untuk merancang dan menyusunatur aktiviti percutian anda	1	2	3	4	5

2. Disebabkan oleh masalah ulser kaki anda, berapa kerapkah anda merasa:

	Tidak sama sekali	Sedikit masa	Kadangkala	Kebanyakan masa	Setiap masa
a. Letih atau penat	1	2	3	4	5
b. Kelesuan	1	2	3	4	5
c. Bermasalah untuk tidur	1	2	3	4	5
d. Sakit ketika berjalan atau berdiri	1	2	3	4	5
e. Sakit pada waktu malam	1	2	3	4	5

3. Disebabkan oleh masalah ulser kaki anda, berapa kerapkah anda:

	Tidak sama sekali	Sedikit masa	Kadangkala	Kebanyakan masa	Setiap masa
a) Perlu bantuan orang lain untuk membantu diri anda sendiri (seperti mandi dan memakai pakaian)	1	2	3	4	5
b) Perlu bantuan orang lain untuk kerja-kerja rumah sepertimemasak, mengemas atau membasuh pakaian	1	2	3	4	5
c) Perlu bantuan untuk keluar daripada rumah	1	2	3	4	5
d) Perlu lebih masa untuk merancang dan menyusun atur kehidupan harian anda	1	2	3	4	5
e) Merasakan setiap perbuatan anda seolah-olah lebih lama untuk dihabiskan daripada biasa.	1	2	3	4	5

4. Disebabkan oleh masalah ulser kaki anda, berapa kerapkah anda berasa :

	Tidak Sama sekali	Sedikit	Sederhana	Agak banyak	Amat sangat
a) Marah kerana anda tidak boleh membuat perkara yang anda mahu lakukan.	1	2	3	4	5
b) Kecewa kerana orang lain melakukan untuk anda perkara-perkara yang anda sepatutnya lakukan sendiri.	1	2	3	4	5
c) Kecewa kerana tidak dapat membuat perkara yang anda mahu lakukan.	1	2	3	4	5
d) Risau yang ulser kaki anda tidak akan sembuh	1	2	3	4	5
e) Risau yang kaki anda mungkin akan dipotong/amputasi.	1	2	3	4	5
f) Risau terhadap kecederaan kaki anda	1	2	3	4	5
g) Tertekan kerana anda tidak boleh membuat perkara yang anda mahu lakukan.	1	2	3	4	5
h) Risau tentang mendapat ulser pada masa akan datang	1	2	3	4	5
i) Marah kerana ini terjadi kepada anda	1	2	3	4	5
j) Kecewa kerana mengalami kesulitan untuk bergerak ke mana-mana.	1	2	3	4	5

5. Disebabkan oleh masalah ulser kaki anda, berapa kerapkah anda berasa terganggu dengan:	Tidak Sama sekali	Sedikit	Sederhana	Agak banyak	Amat sangat
a) Perlu mengelak tekanan ke atas kaki yang berulser.	1	2	3	4	5
b) Jumlah masa yang diperlukan untuk penjagaan ulser kaki anda (termasuk menukar balutan, menunggu jururawat dan memastikan bahagian yang berulser sentiasa bersih).	1	2	3	4	5
c) Rupa, bau dan lelehan dari ulser anda.	1	2	3	4	5
d) Perlu bergantung kepada orang lain untuk menjaga ulser kaki anda.	1	2	3	4	5

Bahagian Lima : Soal Selidik McGill mengenai Kesakitan- Versi Pendek (SF-MPQ) Form X

3 ☐ **Not Done**

A. SILA GAMBARKAN KESAKITAN YANG ANDA ALAMI PADA MINGGU LEPAS. *(✓ satu kotak untuk setiap pilihan jawapan.)*

		Tiada	Ringan	Sederhana	Teruk
1.	Berdenyut-denyut	0 ☐	1 ☐	2 ☐	3 ☐
2.	Mencucuk-cucuk	0 ☐	1 ☐	2 ☐	3 ☐
3.	Menikam	0 ☐	1 ☐	2 ☐	3 ☐
4.	Menusuk	0 ☐	1 ☐	2 ☐	3 ☐
5.	Mengejangkan	0 ☐	1 ☐	2 ☐	3 ☐
6.	Mencengkam dan berlarutan	0 ☐	1 ☐	2 ☐	3 ☐
7.	Panas membakar	0 ☐	1 ☐	2 ☐	3 ☐
8.	Sakit dan lenguh-lenguh	0 ☐	1 ☐	2 ☐	3 ☐
9.	Berat	0 ☐	1 ☐	2 ☐	3 ☐
10.	Sensitif	0 ☐	1 ☐	2 ☐	3 ☐
11.	Bagaikan hendak pecah	0 ☐	1 ☐	2 ☐	3 ☐
12.	Meletihkan dan melesukan	0 ☐	1 ☐	2 ☐	3 ☐
13.	Meloyakan	0 ☐	1 ☐	2 ☐	3 ☐
14.	Menakutkan	0 ☐	1 ☐	2 ☐	3 ☐
15.	Menyeksakan	0 ☐	1 ☐	2 ☐	3 ☐

B. NILAIKAN TAHAP KESAKITAN YANG ANDA ALAMI PADA MINGGU LEPAS

Garisan berikut mewakili tahap kesakitan yang semakin bertambah daripada "tidak sakit" kepada "sakit paling teruk yang tidak dapat digambarkan". Letakkan satu garis melintang (|) di tempat yang paling tepat menggambarkan kesakitan anda **pada minggu lepas**.

Tiada Sakit

Sakit paling teruk yang tidak dapat digambarkan

Score in mm *(Investigator's use only)*

C. TAHAP KESAKITAN SEKARANG

0 ☐ Tiada Sakit
1 ☐ Ringan
2 ☐ Tidak Menyelesakan
3 ☐ Merunsingkan
4 ☐ Dahsyat
5 ☐ Amat Tak Tertanggung

Bahagian enam: Katz Index of Independence in Activities of Daily Living (ADL)

Aktiviti- aktiviti Mata (1 or 0)	**SENDIRI:** **(1 MATA)** TANPA pengawasan, arahan atau pembantu	**DIBANTU:** **(0 MATA)** DENGAN pengawasan, arahan, pembantu atau bantuan sepenuhnya.
MANDI MATA: ___	(1 MATA) Mandi sendiri sepenuhnya atau perlu bantuan untuk satu anggota badan sahaja seperti belakang badan, alat sulit atau cacat anggota.	(0 MATA) Perlu bantuan ketika mandi untuk lebih daripada satu anggota badan, keluar masuk tab mandi atau bilik air. Memerlukan bantuan untuk mandi sepenuhnya.
BERPAKAIAN MATA: ___	(1 MATA) Mengambil sendiri pakaian daripada almari dan laci dan seterusnya memakai pakaian dengan lengkap. Mungkin perlu bantuan untuk mengikat tali kasut.	(0 MATA) Perlu bantuan untuk menyarung pakaian ke badan atau perlu bantuan sepenuhnya untuk memakai pakaian dengan lengkap.
KETANDAS POINTS: ___	(1 MATA) Pergi ke tandas, duduk dan bangun, menyusun pakaian, membersihkan alat sulit tanpa bantuan sepenuhnya.	(0 MATA) Perlu bantuan untuk ke tandas, membersihkan diri atau hanya mampu menggunakan bekas najis yang disediakan.
PEMINDAHAN POINTS: ___	(1 MATA) Bergerak antara katil dan kerusi tanpa bantuan. Bantuan secara mekanikal adalah diterima.	(0 MATA) Perlu bantuan untuk bergerak antara katil dan kerusi atau bantuan sepenuhnya untuk bergerak..
PERKUMUHAN POINTS: ___	(1 MATA) Mampu mengawal sendiri proses perkumuhan air kecil atau besar.	(0 MATA) Sebahagian atau langsung tidak mampu mengawal proses perkumuhan.
MAKAN POINTS: ___	(1 MATA) Mampu menyuap makanan sendiri dari pinggan ke mulut tanpa bantuan. Penyediaan makanan mungkin dilakukan oleh pihak lain.	(0 MATA) Memerlukan sebahagian atau bantuan sepenuhnya untuk menyuap atau menggunakan tiub untuk makan.

JUMLAH MATA: _____

Bahagian tujuh: Skala Lawton Instrumental Activities of Daily Living (IADL)
Soalan-soalan berikut adalah tentang kemampuan anda menjalani rutin harian secara bersendiri.
Baca setiap soalan dan berikan jawapan dengan membulatkan SATU nombor sahaja.

A. Kemampuan Menggunakan Telefon

1. Mengendalikan telefon dengan sendiri; mencari dan mendail nombor telefon	1
2. Mendail beberapa nombor telefon yang diketahui dan diingati	1
3. Menjawab panggilan sahaja, tetapi tidak mendail nombor	1
4. Tidak menggunakan telefon langsung	0

B. Membeli-belah

1. Menguruskan keperluan untuk membeli-belah tanpa pertolongan	1
2. Membuat pembelian kecil-kecilan tanpa pertolongan	0
3. Perlu ditemani ketika membeli-belah	0
4. Tidak mampu untuk membeli-belah langsung	0

C. Penyediaan makanan

1. Merancang, menyediakan, dan menghidangkan makanan dengan secukupnya tanpa pertolongan.	1
2. Menyediakan makanan dengan cukup jika bahan-bahan disediakan	0
3. Memanaskan dan menyiapkan makanan yang sedia dihidang atau menyediakan makanan tetapi tidak memenuhi keperluan diet	0
4. Makanan perlu disediakan dan dihidang.	0

D. Penjagaan rumah

1. Membersihkan rumah secara sendiri dan dibantu jika melibatkan kerja-kerja berat	1
2. Melakukan rutin kerja ringan seperti membasuh pinggan mangkuk dan mengemas katil	1
3. Melakukan rutin kerja ringan, tetapi tidak berupaya untuk mencapai kebersihan yang sepatutnya.	1
4. Memerlukan bantuan untuk semua kerja-kerja penjagaan rumah	1
5. Tidak membuat sebarang kerja rumah	0

E. Membasuh pakaian

1. Membasuh semua pakaian sendiri	1
2. Membasuh pakaian kecil seperti stoking, sarung kaki dan sebagainya	1
3. Semua pakaian dibasuh oleh orang lain	0

F. Jenis pengangkutan

1.	Bergerak sendiri menggunakan pengangkutan awam atau memandu kenderaan sendiri.	1
2.	Menguruskan sendiri perjalanan dengan menggunakan teksi tetapi kurang menggunakan pengangkutan awam yang lain	1
3.	Perjalanan menggunakan pengangkutan awam dengan dibantu atau ditemani oleh orang lain.	1
4.	Perjalanan terhad dengan menaiki teksi atau kereta dengan bantuan orang lain.	0
5.	Tidak membuat perjalanan langsung.	0

G. Bertanggungjawab terhadap Ubat-ubatan Sendiri

1.	Mengambil ubat-ubatan sendiri dengan sukatan dan masa yang dikehendaki dan dengan betul	1
2.	Hanya akan mengambil ubat-ubatan sekiranya telah disiapkan terlebih awal dengan sukatan-sukatan yang telah diasingkan.	0
3.	Tidak berupaya untuk menyediakan ubat-ubatan sendiri.	0

H. Kebolehan untuk Menguruskan kewangan

1.	Menguruskan hal-hal kewangan sendiri (bajet, menulis cek, membayar sewa dan bil, pergi ke bank); sentiasa mengawasi pendapatan yang diterima	1
2.	Menguruskan rutin pembelian harian, tetapi memerlukan bantuan untuk perbankan, pembelian yang banyak dan sebagainya.	1
3.	Tidak berupaya untuk menguruskan kewangan sendiri	0

JUMLAH MATA: _____

Terima kasih atas kerjasama anda

A 4.3: The English version of the participant information sheet

School of Healthcare Sciences
Head of School and Dean Professor Sheila Hunt

Ysgol Gwyddorau Gofal Iechyd
Pennaeth yr Ysgol a Decn Yr Athro Sheila Hunt

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Participant information sheet

Please read the following information carefully before reading the consent form

Title of Project: The Impact of Diabetic Foot Ulcer Pain on the Health-Related Quality of Life and Functional Status of Elderly in Malaysia.

Introduction

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends or relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

Similar to other chronic wounds, diabetic foot ulcer may cause debilitating pain. The purpose therefore of this study is to explore the impact of pain, and to improve the health-related quality of life and functional status of elderly people with diabetic foot ulcers who experience pain.

Why have I been chosen for this study?

You have been invited to participate in this study because you are an elderly patient with a diabetic foot ulcer.

Do I have to take part?

No. Participation in this study is entirely voluntary. You can decide to withdraw at any time and this will not disadvantage you in any way throughout your treatment.

What will happen to me if I take part?

If you decide to take part in the study, you will be asked to complete questionnaires that ask about the level and characteristic of the pain, your health-related quality of life and your ability to perform normal activities daily living such as bathing. The questionnaire will take approximately 45 to 60 minutes to complete. The researcher will also read your medical notes and record relevant clinical information.

Expenses and payments?

You will not be paid for your participation in the study.

Are there any disadvantages or risks in taking part in this study?

There are no anticipated disadvantages or risks in taking part in this study; however participation will require a certain amount of time commitment on your part. If any issues arise as a result of you taking part in the study, you may contact the researcher to help you with your issue. If there are questions that you find distressing or intrusive, you are free to not answer those questions or to withdraw from participating.

What are the benefits?

There are no direct benefits to you in taking part in the study. However, the findings from this study will be used to improve nursing practice and to ultimately improve the quality of patient care.

Who will know I am taking part in this study?

No one other than the researcher will know that you have taken part as all findings will be kept completely confidential.

What will happen if I don't want to carry on with the study?

You can withdraw at any time without penalty. If you do withdraw, data collected up to that point will be used in the study unless you request otherwise.

What happens if there is a problem?

If you have a concern about any aspect of the study, you should ask to speak to the researcher who will do their best to answer your questions

Will my taking part in this study be kept confidential?

All the information will be kept strictly confidential. Your identity will be protected as participants' names will not be used in any written reports or presentations from the study.

The procedures the researcher will follow to handle, process, store and destroy all of the information obtain about you will follow Cardiff University policies, and fulfill the requirements of the Data Protection Act 1998.

Following Cardiff University guidelines, all paper and electronic records associated with this study will be securely stored for a period of 15 years from the date of the last publication which uses data obtained during this investigation. After this time all records will be permanently destroyed. After completing the studies in Cardiff University, all information gathered in this study will be passed to the care of a designated custodian. This person will have the responsibility to oversee the continued secure storage of all records, to maintain confidentiality, and to permanently destroy all paper and electronic files at the designated time.

Who has reviewed the study?

The study was given a favourable ethical opinion from School of Healthcare Sciences Research Ethics Committee and Malaysia Medical Research Ethics Committee (MREC).on this study.

Further information and contact details:

For further information on this study you are invited to contact either my academic supervisor or myself using the following details:

Principal researcher:

AniawanisMakhtar
PhD student
Cardiff University School of Healthcare Sciences
College of Biomedical and Life Sciences
Eastgate House
35-43 Newport Road
Cardiff. CF24 0AB

Telephone: 0192334978

Email: MakhtarA@cardiff.ac.uk

Academic Supervisors:

Professor Dinah Gould

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Dr.Sally Anstey

Lecturer
Cardiff University School of Healthcare Sciences
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Tel: 02920 917718

Email: AnsteyS1@cardiff.ac.uk

Or

National Medical Research Malaysia,
(NIH Secretariat, Ministry of Health Malaysia),
c/o Institute for Health Management,
Jalan Rumah Sakit, Bangsar,50900 Kuala Lumpur.
Phone: 03 - 2287 4032 Fax: 03 - 2287 4030
Email: URL: http://www.nih.gov.my

Please keep a copy of this information sheet.

Thank you for taking the time to read this information sheet and considering taking part in this study.

A 4.4: The Malay version of the participant information sheet

School of Healthcare Sciences
Head of School and Dean Professor Sheila Hunt

Ysgol Gwyddorau Gofal Iechyd
Pennaeth yr Ysgol a Deon Yr Athro Sheila Hunt

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Lembaran maklumat peserta

Sila baca maklumat di bawah dengan teliti sebelum membaca borang persetujuan

Tajuk Projek: Impalikasi kesakitan akibat ulser kaki diabetes (*diabetic foot ulcer*) terhadap kualiti hidup dan kehidupan seharian bagi warga tua di Malaysia.

Pengenalan
Anda telah dijemput untuk mengambil bahagian dalam kajian ini. Sebelum anda membuat keputusan, adalah penting untuk anda memahami tujuan kajian ini dilakukan dan apakah perkara yang terlibat dalam kajian ini. Anda diberi masa untuk membaca arahan dengan teliti dan berbincang dengan rakan-rakan atau saudara-mara anda jika anda perlu rujuk kepada mereka. Sebarang persoalan yang anda tidak jelas atau tidak faham adalah dialu-alukan untuk anda bertanya kepada pihak kami untuk mengetahui maklumat dengan lebih lanjut. Sila ambil masa untuk membuat keputusan sama ada mahu meneruskan atau tidak mengambil bahagian dalam kajian ini.

Apakah tujuan diadakan kajian ini?
Ulser kaki akibat diabetes/kencing manis ialah penyakit yang sama seperti kecederaan kronik yang lain yang akan menyebabkan kesakitan. Tujuan kajian ini adalah untuk mengkaji kesan terhadap kesakitan, dan memperbaiki kualiti hidup dan kehidupan seharian warga tua yang mengalami kesakitan ulser kaki akibat diabetes/kencing manis.

Mengapakah saya dipilih untuk terlibat dalam kajian ini?
Anda telah dijemput untuk mengambil bahagian dalam kajian ini kerana anda adalah salah seorang daripada warga tua yang mengalami ulser kaki akibat diabetes/kencing manis.

Adakah saya perlu mengambil bahagian?
Tidak. Pengambilan bahagian dalam kajian ini ialah secara sukarela. Anda berhak untuk menentukan sama ada untuk tidak mengambil bahagian dalam kajian ini dan ini tidak akan mengurangkan kemudahan anda dalam apa-apa rawatan anda.

Apakah yang akan terjadi sekiranya saya mengambil bahagian?
Jika anda mengambil keputusan untuk mengambil bahagian dalam kajian ini, anda akan disoal tentang peringkat dan ciri-ciri kesakitan anda, berkenaan kualiti kesihatan anda dan kemampuan untuk melakukan aktiviti seharian yang normal seperti mandi. Soal selidik ini akan mengambil masa kira-kira 45 hingga 60 minit untuk dilengkapkan. Penyelidik akan membaca nota perubatan dan rekod anda yang berkaitan dengan maklumat klinikal.

Perbelanjaan dan bayaran?
Anda tidak akan dikenakan bayaran berhubung dengan menjawab soal kaji selidik ini.

Adakah terdapat sebarang kekurangan atau risiko dalam mengambil bahagian dalam kajian ini?
Tidak terdapat sebarang risiko yang akan dijangkakan dalam mengambil bahagian dalam kajian ini. Walaubagaimanapun, pengambilan bahagian ini akan memerlukan komitmen masa yang tertentu untuk anda menyelesaikannya. Jika terdapat sebarang isu yang timbul berhubung dengan ana mengambil bahagian dalam kajian ini, anda boleh berhubung dengan penyelidik untuk membantu anda dengan isu anda. Jika terdapat sebarang kesulitan atau perkara yang mengganggu anda, anda berhak untuk tidak menjawab soalan-soalan tersebut atau pun mengundur diri daripada menyertai daripada menjawab borang kaji selidik ini.

Apakah manfaat-manfaat yang akan diperoleh?
Tidak terdapat sebarang kelebihan berhubung dengan anda mengambil bahagian dalam kajian ini. Namun, hasil kajian ini akan digunakan untuk memperbaiki mutu kejururawatan dan seterusnya memperbaiki kualiti terhadap penjagaan pesakit.

Siapakah yang akan mengetahui sekiranya saya mengambil bahagian dalam kajian ini?
Tidak terdapat sesiapa melainkan penyelidik sendiri yang akan mengetahui anda telah mengambil bahagian kerana segala hasil kajian ini akan disimpan secara sulit.

Apakah yang akan berlaku jika saya tidak mahu meneruskan kajian ini?
Anda boleh menarik diri tanpa penalti. Jika anda menarik diri, data yang telah diambil akan digunakan melainkan anda berkehendak sebaliknya.

Apakah yang akan berlaku sekiranya terdapat sebarang masalah?
Jika terdapat sebarang kemusykilan di dalam apa-apa aspek kajian ini, anda perlu bercakap kepada penyelidik yang akan sebaik mungkin menjawab pertanyaan anda.

Adakah dengan menyertai kajian ini, maklumat peribadi saya akan dirahsiakan?
Segala maklumat akan disimpan secara sulit. Identiti anda akan dilindungi kerana nama para peserta yang terlibat tidak akan digunakan di dalam mana-mana kajian bertulis mahupun pembentangan daripada kajian ini.

Prosedur penyelidik akan mengikuti bagaimana untuk mengendali, menyimpan, dan menghapuskan segala maklumat mengenai anda selaras dengan polisi Universiti Cardiff, dan memenuhi keperluan dalam Akta Perlindungan Data 1998.

Berikutan dengan garis panduan, segala rekod bertulis dan elektronik berhubung dengan kajian ini akan terjamin disimpan untuk tempoh 15 tahun daripada tarikh terakhir penerbitan yang menggunakan data yang diperoleh daripada penyelidikan ini. Kemudian segala rekod akan dilupuskan secara kekal. Setelah menyelesaikan penyelidikan di Universiti Cardiff, segala maklumat yang didapati akan diserahkan di bawah jagaan penyelia yang ditetapkan. Penyelia ini akan mempunyai tanggungjawab untuk menyelia penyimpanan secara selamat tentang segala rekod, mengekalkan kerahsiaan, dan untuk melupuskan semua fail bertulis dan fail elektronik pada masa yang ditetapkan.

Siapakah yang telah meluluskan kajian ini?
Kajian ini telah diluluskan oleh School of Healthcare Sciences Research Ethics Committee. dan Jawatankuasa Etika Penyelidikan Perubatan Malaysia (MREC).

Maklumat lanjut dan butir-butir untuk dihubungi:
Untuk makluamt lanjut tentang kajian ini anda dijemput untuk menghubungi sama ada penyelia akademik atau pun penyelidik sendiri dengan merujuk kepada maklumat di bawah:

Ketua penyelidik:
AniawanisMakhtar
Mahasiswi PhD
Cardiff University School of Healthcare Sciences
College of Biomedical and Life Sciences
Eastgate House
35-43 Newport Road
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Atau

National Medical Research Malaysia,
(NIH Secretariat, Ministry of Health Malaysia),
c/o Institute for Health Management,
Jalan Rumah Sakit, Bangsar,50900 Kuala Lumpur.
Phone: 03 - 2287 4032 Fax: 03 - 2287 4030
Email: URL: http://www.nih.gov.my

Sila simpan salinan lembaran maklumat ini.

Terima kasih kerana meluangkan masa untuk membaca lembaran maklumat ini dan mempertimbang untuk mengambil bahagian dalam kajian ini.

A 4.5: The English version of the consent

School of Healthcare Sciences
Head of School and Dean Professor Sheila Hunt

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Consent form

Title of Project: The Impact of Diabetic Foot Ulcer Pain on the Health-Related Quality of Life and Functional Status of Elderly in Malaysia

I have read the information sheet and understand that.

		Please initial box
1.	This research is to investigate the impact of diabetic foot ulcer pain on the health-related quality of life and functional status.	☐
2.	I will be asked to fill out a questionnaire about my level of pain and its characteristics, health-related quality of life and functional status.	☐
3.	I understand that the researcher will obtain relevant clinical information about me from my medical notes.	☐
4.	The questionnaire will take approximately 45 to 60 minutes to complete.	☐
5.	Any reports or publications resulting from this study will be reported in general terms and will not involve me being identified.	☐
6.	I understand that relevant sections of data collected during the study may be looked at by responsible individuals from Cardiff University, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
7.	The data will be kept confidential.	☐

8. I may request to withdraw at any time without needing to explain any reason. ☐

9. No loss of benefit, treatment or penalty will occur as a result of my withdrawal. ☐

I have read the information sheet and consent form. I agree to participate in this study and give my consent freely. I understand that the study will be carried out as described in the information statement, a copy of which I have retained. I realise that I can withdraw from the study at any time and that I do not have to give any reasons for withdrawing. I have had all questions answered to my satisfaction.

.....	.....	.....
Name of Participant	Signature	Date
.....	.....	.....
Name of Researcher	Signature	Date

When completed, 1 for participant; 1 for researcher

A 4.6: The Malay version of the consent

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Head of School and Dean Professor Sheila Hunt

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Borang persetujuan

Tajuk Projek: Implikasi kesakitan akibat ulser kaki diabetes (*diabetic foot ulcer*) terhadap kualiti hidup dan kehidupan seharian bagi warga tua di Malaysia.

Saya telah membaca maklumat borang ini dan memahami pengisian borang ini.

		Sila tanda di dalam kotak
1.	Kajian ini dilakukan untuk menyelidik impak kesakitan akibat ulser kaki diabetes (*diabetic foot ulcer*) terhadap kualiti hidup dan kehidupan seharian.	☐
2.	Saya akan disoal untuk mengisi borang kaji selidik tentang tahap kesakitan dan ciri-cirinya, kualiti hidup dan kehidupan seharian.	☐
3.	Saya memahami bahawa penyelidik akan mendapatkan maklumat klinikal yang berkaitan daripada nota perubatan saya.	☐

4.	Soal kaji selidik akan mengambil masa lebih kurang 45 hingga 60 minit untuk diselesaikan.	☐
5.	Sebarang laporan atau penerbitan berhubung dengan hasil kajian ini akan dilaporkan dalam isitilah umum dan tidak akan melibatkan pengenalpastian saya.	☐
6.	Saya memahami bahawa seksyen yang berkaitan dengan data diperoleh sepanjang kajian ini dilakukan mungkin akan dilihat oleh individu yang bertanggungjawab daripada Universiti Cardiff, di mana ianya relevan dengan penglibatan saya dalam kajian ini. Saya memberi kebenaran untuk individu tersebut mengakses rekod-rekod saya.	☐
7.	Data ini akan disimpan secara sulit.	☐
8.	Saya berkemungkinan akan menarik diri pada bila-bila masa tanpa perlu menjelaskan alasan saya.	☐
9.	Tiada kerugian manfaat, rawatan atau penalti yang akan terjadi akibat daripada penarikan diri saya.	☐

Saya telah membaca maklumat lembaran dan borang persetujuan. Saya bersetuju untuk mengambil bahagian dalam kajian ini dan memberikan persetujuan saya secara rela. Saya memahami bahawa kajian ini akan dijalankan sebagaimana yang telah dijelaskan di dalam lembaran maklumat ini, salinan yang saya telah simpan. Saya menyedari bahawa saya boleh menarik diri daripada kajian ini pada bila-bila masa dan saya tidak perlu memberikan sebab-sebab untuk menarik diri. Saya telah menjawab kesemua soalan secara memuaskan.

.....	.....	.....
Nama peserta	Tandatangan	Tarikh
.....	.....	.....
Nama Penyelidik	Tandatangan	Tarikh

Apabila lengkap, 1 untuk peserta; 1 untuk penyelidik

Appendix 5: Testing underlying assumptions of normality and multiple linear regression

Figure A5. 1 Non-normal distribution of short-form McGill pain questionnaire

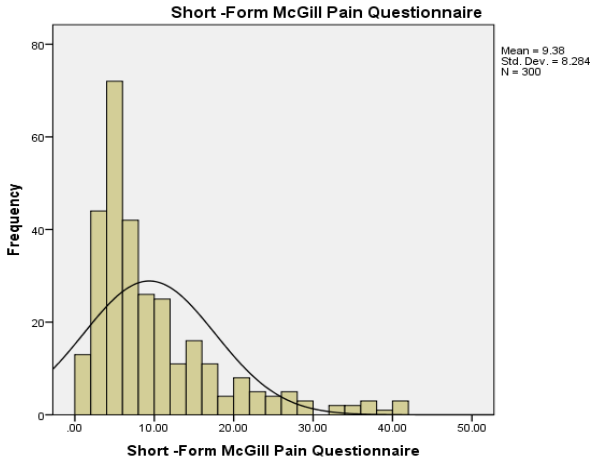

Figure A5. 2 Normal distribution of diabetic foot ulcer scale short-form

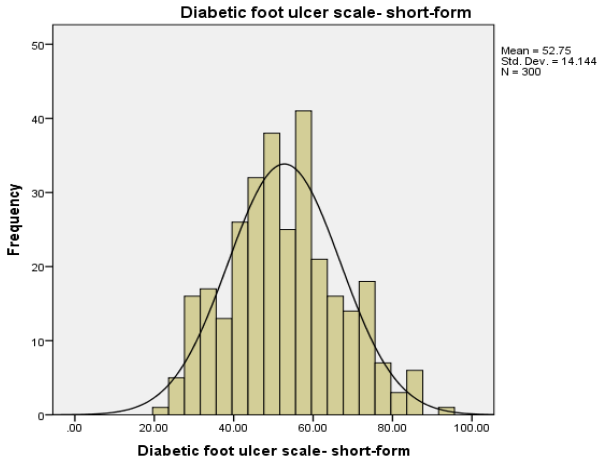

Figure A5. 3 Normal distribution of the medical outcomes study SF-36 item short-form health survey

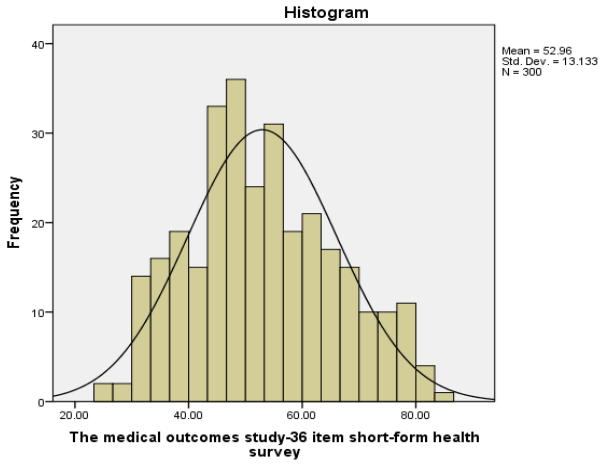

Figure A5. 4 Non-normal distribution of Katz activity daily living

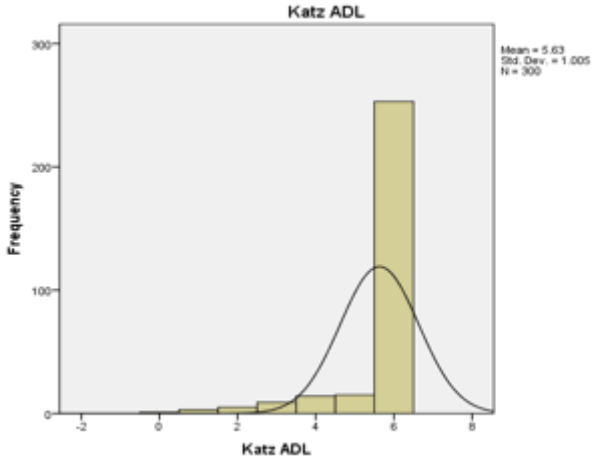

Figure A5. 5 Normal distribution of the medical outcomes study Lawaton instrumental activity daily living

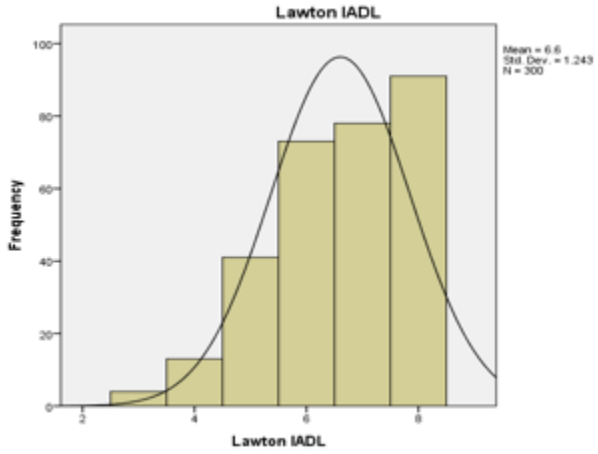

Figure A5. 6 Distribution of study predictors

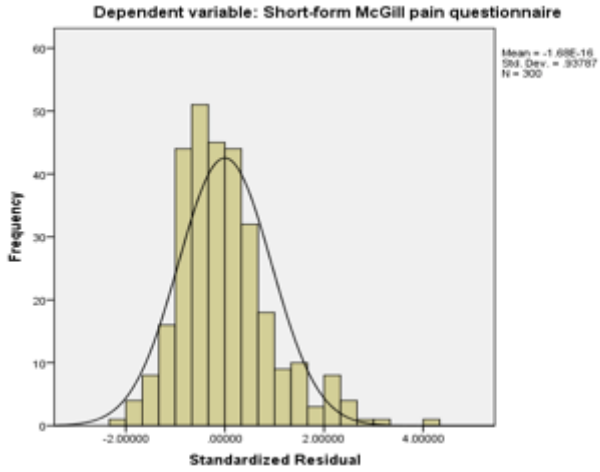

Figure A5. 7 Residuals scatter plot of the predictors